CC:

Manupella, Matthew [Manupella.Matthew@epa.gov] From:

Sent: 5/10/2018 12:49:25 PM

To: Jennings, Susan [Jennings.Susan@epa.gov]; Carl Schultze [Carl.P.Schulze@aphis.usda.gov]; Julius Fajardo

[Julius.Fajardo@ARS.USDA.GOV]; Heather.Harbottle@fda.hhs.gov; Jean Patel [vzp4@cdc.gov];

Jeff.Gilbert@fda.hhs.gov; Michael Craig [bez7@cdc.gov]; Rose Hammond [Rose.Hammond@ARS.USDA.GOV]; Zinn, Nicole [Zinn.Nicole@epa.gov]; Costello, Kevin [Costello.Kevin@epa.gov]; Garvie, Heather [Garvie.Heather@epa.gov];

Johnson, Hope [Johnson.Hope@epa.gov]; Collins, Samantha [collins.samantha@epa.gov]; Kaul, Monisha [Kaul.Monisha@epa.gov]; Kough, John [Kough.John@epa.gov]; Chandgoyal, Tara [Chandgoyal.Tara@epa.gov] Giles-Parker, Cynthia [Giles-Parker.Cynthia@epa.gov]; Cook, Colwell [cook.colwell@epa.gov]; Adeeb, Shanta

[Adeeb.Shanta@epa.gov]; Smith, Charles [Smith.Charles@epa.gov]; Sow, Fatima [Sow.Fatima@epa.gov]

RE: Interagency Meeting on Antibiotic Resistance and Pesticides Subject: Attachments: Antibiotics in Registration Review for Federal Parteners May 9.docx

My apologies, this is the most recent version.

From: Manupella, Matthew

Sent: Thursday, May 10, 2018 8:35 AM

To: Jennings, Susan < Jennings.Susan@epa.gov>; Carl Schultze < Carl.P.Schulze@aphis.usda.gov>; Julius Fajardo <Julius.Fajardo@ARS.USDA.GOV>; Heather.Harbottle@fda.hhs.gov; Jean Patel <vzp4@cdc.gov>; Jeff.Gilbert@fda.hhs.gov; Michael Craig <bez7@cdc.gov>; Rose Hammond <Rose.Hammond@ARS.USDA.GOV>; Zinn, Nicole <Zinn.Nicole@epa.gov>; Costello, Kevin <Costello.Kevin@epa.gov>; Garvie, Heather <Garvie.Heather@epa.gov>; Johnson, Hope <Johnson.Hope@epa.gov>; Collins, Samantha <collins.samantha@epa.gov>; Kaul, Monisha <Kaul.Monisha@epa.gov>; Kough, John <Kough.John@epa.gov>; Chandgoyal, Tara <Chandgoyal.Tara@epa.gov> Cc: Giles-Parker, Cynthia <Giles-Parker.Cynthia@epa.gov>; Cook, Colwell <cook.colwell@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Smith, Charles <Smith.Charles@epa.gov>; Sow, Fatima <Sow.Fatima@epa.gov> Subject: RE: Interagency Meeting on Antibiotic Resistance and Pesticides

Sorry this is a little last minute, but I've attached a summary for the registration review discussion.

I will bring copies.

Thanks, Matt

----Original Appointment----

From: Jennings, Susan

10:40

**Sent:** Wednesday, May 9, 2018 6:05 PM

To: Jennings, Susan; Carl Schultze; Julius Fajardo; Heather. Harbottle@fda.hhs.gov; Jean Patel; Jeff. Gilbert@fda.hhs.gov; Michael Craig; Rose Hammond; Manupella, Matthew; Zinn, Nicole; Costello, Kevin; Garvie, Heather; Johnson, Hope;

Collins, Samantha; Kaul, Monisha; Kough, John; Chandgoyal, Tara

Cc: Giles-Parker, Cynthia; Cook, Colwell; Adeeb, Shanta; Smith, Charles; Sow, Fatima

Subject: Interagency Meeting on Antibiotic Resistance and Pesticides

When: Thursday, May 10, 2018 9:30 AM-12:30 PM (UTC-05:00) Eastern Time (US & Canada).

Where: DCRoomPYS8100/Potomac-Yard-One

Having received no comments on the agenda, I guess it's ok. So for tomorrow, our agenda will be:

9:30 Update from CDC, FDA and USDA

10:00 Update from the Vancouver meeting (CDC) 10:20 Registration update on Registrations (RD)

Uses for Registration Review (PRD)

10:55 AR Reports, what changes in Registration Review in ARRT assessments (John Kough)

- 11:20 Mitigation options for Registration Review (PRD)
- 11:50 Next Steps (are we all ok w/ tabling the joint statement?)

CC:

From: Manupella, Matthew [Manupella.Matthew@epa.gov]

**Sent**: 5/10/2018 12:34:39 PM

To: Jennings, Susan [Jennings.Susan@epa.gov]; Carl Schultze [Carl.P.Schulze@aphis.usda.gov]; Julius Fajardo

[Julius.Fajardo@ARS.USDA.GOV]; Heather.Harbottle@fda.hhs.gov; Jean Patel [vzp4@cdc.gov];

Jeff.Gilbert@fda.hhs.gov; Michael Craig [bez7@cdc.gov]; Rose Hammond [Rose.Hammond@ARS.USDA.GOV]; Zinn, Nicole [Zinn.Nicole@epa.gov]; Costello, Kevin [Costello.Kevin@epa.gov]; Garvie, Heather [Garvie.Heather@epa.gov];

Johnson, Hope [Johnson.Hope@epa.gov]; Collins, Samantha [collins.samantha@epa.gov]; Kaul, Monisha [Kaul.Monisha@epa.gov]; Kough, John [Kough.John@epa.gov]; Chandgoyal, Tara [Chandgoyal.Tara@epa.gov] Giles-Parker, Cynthia [Giles-Parker.Cynthia@epa.gov]; Cook, Colwell [cook.colwell@epa.gov]; Adeeb, Shanta

[Adeeb.Shanta@epa.gov]; Smith, Charles [Smith.Charles@epa.gov]; Sow, Fatima [Sow.Fatima@epa.gov]

**Subject**: RE: Interagency Meeting on Antibiotic Resistance and Pesticides **Attachments**: Antibiotics in Registration Review for Federal Parteners May 9.docx

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I will bring copies.

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From: Jennings, Susan

Sent: Wednesday, May 9, 2018 6:05 PM

**To:** Jennings, Susan; Carl Schultze; Julius Fajardo; Heather.Harbottle@fda.hhs.gov; Jean Patel; Jeff.Gilbert@fda.hhs.gov; Michael Craig; Rose Hammond; Manupella, Matthew; Zinn, Nicole; Costello, Kevin; Garvie, Heather; Johnson, Hope;

Collins, Samantha; Kaul, Monisha; Kough, John; Chandgoyal, Tara

Cc: Giles-Parker, Cynthia; Cook, Colwell; Adeeb, Shanta; Smith, Charles; Sow, Fatima

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- 11:50 Next Steps (are we all ok w/ tabling the joint statement?)

From: Jennings, Susan [Jennings.Susan@epa.gov]

**Sent**: 9/30/2016 3:08:23 PM

To: Carl Schultze [Carl.P.Schulze@aphis.usda.gov]; Fajardo, Julius [Julius.Fajardo@ARS.USDA.GOV];

Heather.Harbottle@fda.hhs.gov; Jean Patel [vzp4@cdc.gov]; Jeff.Gilbert@fda.hhs.gov; Michael Craig

[bez7@cdc.gov]; Rose Hammond [Rose.Hammond@ARS.USDA.GOV]

CC: Johnson, Marion [Johnson.Marion@epa.gov]; Maignan, Tawanda [Maignan.Tawanda@epa.gov]; Giles-Parker,

Cynthia [Giles-Parker.Cynthia@epa.gov]; Johnson, Marion [Johnson.Marion@epa.gov]; Garvie, Heather

[Garvie.Heather@epa.gov]; Jones, Arnet [Jones.Arnet@epa.gov]; Chandgoyal, Tara [Chandgoyal.Tara@epa.gov]; Yourman, Leonard [Yourman.Leonard@epa.gov]; Britton, Cathryn [Britton.Cathryn@epa.gov]; Manupella, Matthew

[Manupella.Matthew@epa.gov]; Leshin, Jonathan [Leshin.Jonathan@epa.gov]; Collins, Samantha [collins.samantha@epa.gov]; Conrath, Andrea B [Conrath.Andrea@epa.gov]; Kaul, Monisha

[Kaul.Monisha@epa.gov]; Herndon, George [Herndon.George@epa.gov]; Kough, John [Kough.John@epa.gov]

Subject: Action Items from AR Interagency Meeting

Attachments: Antibiotic Resistance Interagency Meeting Minutes 09-28-16.docx

Hi,

Thanks to all for helping to make Wednesday's meeting so productive. I have attached a copy of the meeting minutes. If everyone could please review and make sure that I have not overlooked, misinterpreted, or erred on anything I would truly appreciate it.

The minutes detail the action items (highlighted with \*\*\*), but for clarity I am also going to include them here (again, please let me know if this list can be improved):

# Deliberative Process / Ex. 5

I'm looking forward to working with all of you on this.

Thanks,

Susan.

Susan Jennings Senior Advisor for Public Health Office of Pesticide Programs (706) 355-8574 (office) (703) 216-8627 (cell)

# **Antibiotic Resistance Interagency Meeting Minutes**

September 30, 2016

### **FDA Report Out:**

FDA presented an overview of their efforts to minimize the impact of antibiotics in livestock from promoting antibiotic resistance. By January, 2017, they expect to have no antibiotics licensed for weight gain. FDA looks at all compounds for antibiotic resistance, not only antibiotics (they presented an example of hydrogen peroxide). FDA also relies up Guideline 159 to evaluate potential residues consumed by humans through meat, milk, or eggs from treated livestock. (Dr. Jeffrey Gilbert and Dr. Heather Hardbottle from FDA participated).

### USDA Report Out:

Discussed use of bacterial static compounds and the role of suppressing bacteria in the host organism. USDA also discussed some of the research being conducted into the various types of control, including: injection and phage research (1 is registered in BPPD). (Dr. Rose Hammon, Dr. Carl Shultze, Dr. Julius Fajardo from USDA participated).

### **CDC Report Out**

CDC discussed their various surveillance measures and the importance of antibiotic stewardship. NARMS tracks bacterial pathogens in animal food. Includes shigella, MRSA and other healthcare and community spread pathogens. CDC also captures antibiotic-resistant infections in hospitals, characterizes bacterial isolates, and measures antibiotic use in the healthcare system. CDC has seen increasing threats from antibiotic resistance and new types of resistance mechanisms. There is also concern about hospital effluent into the environment. (Dr. Michael Craig and Dr. Jean Patel participated from CDC).

Discussion about how to assess potential for antibiotic resistance from antibiotics used in crops

Current levels of persistence: about 25 day half-life for aminoglycosides and 12 – 26 days for streptomycin.

# **Deliberative Process / Ex. 5**

Risk in Greenhouse: Group believes that it is only a concern to the extent that it's a risk directly to humans or in a transfer from greenhouse to real world.

Limitations for yearly restriction (do not use on same land in less than a four year cycle to encourage rotation and other physical means of control) was determined not to be feasible. Challenges discussed included enforceability, compliance, and even whether the growers would know if it had been used in

[PAGE \\* MERGEFORMAT]

the previous year. USDA pointed out that these diseases are frequently transmitted via the seed so that even if a field is clear one year, the bacteria could be reintroduced the next. CDC felt that putting something unenforceable on the label could lead to a false sense of accomplishment.

### **Monitoring Data**

The group discussed the feasibility and benefit of monitoring data. CDC does not believe any of the monitoring data submitted thus far have been very useful. EPA scientists for the most part concurred. Most powerful tool is sequencing; however, sequencing will not detect novel modes of resistance, the researcher needs to know what they are looking for.

# **Deliberative Process / Ex. 5**

# **Deliberative Process / Ex. 5**

(FDA may have a template to start with).

[PAGE \\* MERGEFORMAT]

[ PAGE \\* MERGEFORMAT ]

From: Giles-Parker, Cynthia [Giles-Parker.Cynthia@epa.gov]

**Sent**: 7/5/2017 3:34:14 PM

To: Jennings, Susan [Jennings.Susan@epa.gov]; Kough, John [Kough.John@epa.gov]; Collins, Samantha

[collins.samantha@epa.gov]; Chandgoyal, Tara [Chandgoyal.Tara@epa.gov]; Carl Schultze

[Carl.P.Schulze@aphis.usda.gov]; Julius Fajardo [Julius.Fajardo@ARS.USDA.GOV]; Heather.Harbottle@fda.hhs.gov;

Jean Patel [vzp4@cdc.gov]; Jeff.Gilbert@fda.hhs.gov; Michael Craig [bez7@cdc.gov]; Rose Hammond

[Rose.Hammond@ARS.USDA.GOV]

CC: Garvie, Heather [Garvie.Heather@epa.gov]; Johnson, Hope [Johnson.Hope@epa.gov]; Sow, Fatima

[Sow.Fatima@epa.gov]

**Subject**: RE: Trying to schedule the July interagency (time sensitive)

I can make myself available for the proposed dates and times. July 18<sup>th</sup> is probably the best date.

From: Jennings, Susan

Sent: Wednesday, July 05, 2017 9:55 AM

To: Kough, John <Kough.John@epa.gov>; Collins, Samantha <collins.samantha@epa.gov>; Chandgoyal, Tara

<Chandgoyal.Tara@epa.gov>; Carl Schultze <Carl.P.Schulze@aphis.usda.gov>; Julius Fajardo

<Julius.Fajardo@ARS.USDA.GOV>; Heather.Harbottle@fda.hhs.gov; Jean Patel <vzp4@cdc.gov>;

Jeff.Gilbert@fda.hhs.gov; Michael Craig <bez7@cdc.gov>; Rose Hammond <Rose.Hammond@ARS.USDA.GOV>

**Cc:** Giles-Parker, Cynthia < Giles-Parker. Cynthia@epa.gov>; Garvie, Heather < Garvie. Heather@epa.gov>; Johnson, Hope

<Johnson.Hope@epa.gov>

**Subject:** Trying to schedule the July interagency (time sensitive)

Hello all,

Because of various scheduling conflicts, I am going to try again to schedule our interagency meeting to discuss the EPA assessments for streptomycin, kasugamycin, and oxytetracycline.

The only times that I could find are:

Tuesday morning, July 18 from

9 to 11

10 to 12

11 to 1

Wednesday morning, July 19, from:

9 to 11

10 to 12

11 - 1

Thursday, July 20, from 8-10.

I would really appreciate everyone's help in trying to make one of these times work for everyone.

If you each could fill respond to this email asap, I would be very appreciative.

Thanks,

Susan.

Susan Jennings Senior Advisor for Public Health Office of Pesticide Programs (706) 355-8574 (office) (703) 216-8627 (cell)

From: Kough, John [Kough.John@epa.gov]

**Sent**: 7/5/2017 2:08:45 PM

To: Jennings, Susan [Jennings.Susan@epa.gov]; Collins, Samantha [collins.samantha@epa.gov]; Chandgoyal, Tara

[Chandgoyal.Tara@epa.gov]; Carl Schultze [Carl.P.Schulze@aphis.usda.gov]; Julius Fajardo [Julius.Fajardo@ARS.USDA.GOV]; Heather.Harbottle@fda.hhs.gov; Jean Patel [vzp4@cdc.gov];

Jeff.Gilbert@fda.hhs.gov; Michael Craig [bez7@cdc.gov]; Rose Hammond [Rose.Hammond@ARS.USDA.GOV]
Giles-Parker, Cynthia [Giles-Parker.Cynthia@epa.gov]; Garvie, Heather [Garvie.Heather@epa.gov]; Johnson, Hope

[Johnson.Hope@epa.gov]

**Subject**: RE: Trying to schedule the July interagency (time sensitive)

Susan,

CC:

I can be available at any of these times.

John Kough

Sent from my Windows Phone

From: Jennings, Susan Sent: 7/5/2017 9:54 AM

To: Kough, John; Collins, Samantha; Chandgoyal, Tara; Carl Schultze; Julius Fajardo; Heather. Harbottle@fda.hhs.gov;

Jean Patel; Jeff.Gilbert@fda.hhs.gov; Michael Craig; Rose Hammond

Cc: Giles-Parker, Cynthia; Garvie, Heather; Johnson, Hope

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Senior Advisor for Public Health Office of Pesticide Programs (706) 355-8574 (office) (703) 216-8627 (cell)

From: Hammond, Rose [Rose.Hammond@ARS.USDA.GOV]

**Sent**: 7/5/2017 2:02:57 PM

To: Jennings, Susan [Jennings.Susan@epa.gov]; Kough, John [Kough.John@epa.gov]; Collins, Samantha

[collins.samantha@epa.gov]; Chandgoyal, Tara [Chandgoyal.Tara@epa.gov]; Schulze, Carl P - APHIS

[Carl.P.Schulze@aphis.usda.gov]; Julius Fajardo [Julius.Fajardo@ARS.USDA.GOV]; Heather.Harbottle@fda.hhs.gov;

Jean Patel [vzp4@cdc.gov]; Jeff.Gilbert@fda.hhs.gov; Michael Craig [bez7@cdc.gov]

CC: Giles-Parker, Cynthia [Giles-Parker.Cynthia@epa.gov]; Garvie, Heather [Garvie.Heather@epa.gov]; Johnson, Hope

[Johnson.Hope@epa.gov]

**Subject**: RE: Trying to schedule the July interagency (time sensitive)

Dear Susan,

I am available all of those times.

Rose

Dr. Rosemarie W. Hammond, Research Plant Pathologist USDA ARS NEA BARC Molecular Plant Pathology Laboratory Building 004 Room 214 BARC-West 10300 Baltimore Avenue Beltsville, MD 20705 (P) 301-504-5203 (Fax) 301-504-5449 rose.hammond@ars.usda.gov

From: Jennings, Susan [mailto:Jennings.Susan@epa.gov]

**Sent:** Wednesday, July 05, 2017 9:55 AM

**To:** Kough, John; Collins, Samantha; Chandgoyal, Tara; Schulze, Carl P - APHIS; Fajardo, Julius; Heather.Harbottle@fda.hhs.gov; Jean Patel; Jeff.Gilbert@fda.hhs.gov; Michael Craig; Hammond, Rose

**Cc:** Giles-Parker, Cynthia; Garvie, Heather; Johnson, Hope

**Subject:** Trying to schedule the July interagency (time sensitive)

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| Office of Pesticide Programs<br>(706) 355-8574 (office)<br>(703) 216-8627 (cell)   |
|--|
|  |
| This electronic message contains information generated by the USDA solely for the intended recipients. Any unauthorized interception of this message or the use or disclosure of the information it contains may violate the law and subject the violator to civil or criminal penalties. If you believe you have received this message in error, please notify the sender and delete the email immediately. |
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|  |
|  |

If you each could fill respond to this email asap, I would be very appreciative.

Thanks,

Susan.

Susan Jennings

Senior Advisor for Public Health

From: Hill, Shaunta [Hill.Shaunta@epa.gov]

**Sent**: 4/19/2016 6:12:47 PM

To: Patel, Jean (CDC/OID/NCEZID) [vzp4@cdc.gov]; Craig, Michael R. (CDC/OID/NCEZID) [bez7@cdc.gov]; Harbottle,

Heather [Heather.Harbottle@fda.hhs.gov]; Gilbert, Jeffrey M [Jeff.Gilbert@fda.hhs.gov]; Wan, Ellen

(CDC/OID/NCEZID) [gqj0@cdc.gov]

CC: Jennings, Susan [Jennings.Susan@epa.gov]; Kough, John [Kough.John@epa.gov]; Chandgoyal, Tara

[Chandgoyal.Tara@epa.gov]; Hicks, Karen [Hicks.Karen@epa.gov]; Blackwell, Ian [blackwell.ian@epa.gov]

**Subject**: Final meeting minutes 2-10-16 CDC-EPA-FDA teleconference

Attachments: Section 18 citrus 152 review final.pdf; Sec 3 grpfrt tomato strep 152.pdf; Meeting minutes 02102016 EPA-CDC-

FDA\_Final\_031616.pdf

### Hello everyone,

I just realized that I neglected to send the final meeting minutes to everyone concerning our Feb 2016 teleconference. Please see the final version which is attached. I am also including the final 152 reviews for the citrus section 18 (FL) and grapefruit/tomato section 3.

Thank you all for your inputs.

### Regards,

\*

Shaunta Hill-Hammond, Ph. D. Acting Ombudsman Antimicrobials Division, 7510P Office of Pesticide Programs U.S. Environmental Protection Agency

Washington, DC 20460 Tel: 703.347.8961

## EPA - FDA - CDC Teleconference Feb 10, 2016.

Meeting Minutes

### Meeting Participants:

| viceting i articipants.   |
|---|
| EPA – Office of Pesticide Programs  |
| Shaunta Hill, PhD., Plant Pathologist   |
| Fungicide Branch, Registration Division   |
| Karen P. Hicks, Microbiologist, CTT Lead  |
| Product Science Branch, Antimicrobials Division                                 |
| John L. Kough, Ph.D., Biologist   |
| Microbial Pesticides Branch,  |
| Biopesticide and Pollution Prevention Division                                  |
| Tara Chandgoyal, Ph.D., Plant Pathologist                                       |
| Biological Assessment Branch, Biological, Economical, Assessment Division       |
| Susan Jennings, Public Health Coordinator                                       |
| Immediate Office, Registration Division   |
| CDC - National Center for Emerging and Zoonotic Infectious Diseases             |
| Jean Patel, Ph.D., Deputy Director,   |
| Office of Antimicrobial Resistance, Division of Healthcare Quality Promotion    |
| Michael Craig, MPP Program Analyst  |
| Office of Antimicrobial Resistance, Division of Healthcare Quality Promotion    |
| Ellen Wan, Public Health Analyst  |
| Office of Antimicrobial Resistance, Division of Healthcare Quality Promotion    |
| FDA - Office of New Animal Drug Evaluation, Center for Veterinary Medicine, FDA |
| Jeff Gilbert, Ph.D., Microbiologist, Team Leader                                |
| Microbial Food Safety Team  |
| Heather Harbottle, Ph.D., Microbiologist,                                       |
| Microbial Food Safety Team  |
| Meeting Observers:  |
| EPA - Fungicide Branch, Registration Division                                   |
| Fatima Sow  |
| Hope Johnson, PM 21   |
| Cynthia Giles-Parker, Branch Chief  |
| EPA - Pesticide Re-evaluation Division  |
| Cathryn Britton   |
| Matthew Manupella   |
|   |

**Summary:** The Office of Pesticide Programs of the U.S. Environmental Protection Agency held a teleconference with CDC and FDA to discuss pesticide application requests for the antibiotics streptomycin and oxytetracycline. The teleconference was held on February 10, 2016. CDC and FDA participants shared several general points with respect to pesticidal use of streptomycin and oxytetracycline, including new resistance concerns and new drug development. With respect to the pending pesticide applications, EPA shared the proposed risk classification for the grapefruit /tomato Section 3 request. EPA highlighted the application details for the proposed Section 18 request and noted the full assessment was pending. Details of the discussion are listed below.

Meeting Minutes: EPA-CDC-FDA teleconference February 10, 2016 — Page 1 Draft 2/25/16 - Finalized 3/16/16

## General points of the discussion:

- EPA shared that the current applications reference "low usage" comparative to current human or animal use.
  - o CDC/FDA: Although pesticidal uses are lower than therapeutic use, resistance risk is not removed.
    - Low residue concentrations can select for resistance.
    - There is a greater appreciation for resistance development as diagnostic tools have evolved to detect these traits in bacterial populations.
- CDC: New aminoglycosides (plazomicin) are in development. Older tetracyclines (minocycline) are finding use against newly emerging bacterial diseases. Additional pesticidal use of drugs currently used in human medicine could jeopardize the effectiveness of the new tools given increased detection in plasmid mediated transfers.
  - O There is an increased occurrence of infections by *Acinetobacter baumanni*, a bacterial pathogen often found in soil and water, whose last line of defense is tetracycline. Use of oxytetracycline in the environment will directly lead to greater selection for tetracycline resistance in *Acinetobacter* species.
  - There is widespread selection of multidrug resistance plasmids within the Enterobacteriaceae family of bacteria. These bacteria, with plasmid borne resistance, have led to an explosion of infections with carbapenem resistant Enterobacteriaceae (CRE) pathogens recalcitrant to most antibiotic treatments. These plasmids routinely include streptomycin resistance in addition to other classes of antibiotic. Large-scale environmental release, as envisioned in the Florida citrus Section 18 for HLB, would provide abundant selection pressure and favor the increased presence of these multidrug resistance plasmids in CRE as well as other environmental bacteria.
- FDA is proceeding with efforts to increase judicious use of antibiotics. This means that unnecessary or inappropriate use of antibiotics will be avoided. The framework includes the principles of phasing in such measures as 1) limiting medically important antimicrobial drugs to uses in food-producing animals that are considered necessary for assuring animal health; and 2) limiting such drugs to uses in food-producing animals that include veterinary oversight or consultation. Developing strategies for reducing antimicrobial resistance is critically important for protecting both public and animal health. Reference documents include:
  - o GF #209: The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals (FDA notes this is the **Policy** document)
  - GF# 213: New Animal Drugs and New Animal Drug Combination Products
     Administered in or on Medicated Feed or Drinking Water of Food Producing
     Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product
     Use Conditions with GFI #209 (FDA notes this is the Implementation document)
- CDC would recommend Section 18 antibiotic use over Section 3 use where:
  - No good alternatives are available
  - Monitoring data is required

Meeting Minutes: EPA-CDC-FDA teleconference February 10, 2016 — Page 2 Draft 2/25/16 - Finalized 3/16/16

- CDC/FDA: Microbiological impacts of antibiotic use with respect to soil, water and gut environments.
  - Per FDA, gut environments would reflect any antimicrobial residues that may persist on the surface or internally in the fruit.
     When ingested by a person, if this fruit is intended for market, that antimicrobial residue can adversely impact the human intestinal flora by disrupting the colonization barrier or causing microbes in the human intestinal flora to become resistant to the antimicrobial.

If antimicrobial residues persist on or in the fruit and will be used for juice, the juice would need to be tested for antimicrobial residues and any spent product sold for food animal feed may select for antimicrobial resistance in zoonotic pathogens of human health concern in the food animal.

Residues can also act as an allergen to susceptible populations. FDA's GFI #159 addresses antimicrobial residues in edible tissues and the impact on the human intestinal microflora. This comment pertains to both antimicrobials discussed.

http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM124674.pdf.

- o All possible labeling mitigations/limitations are included
- The proposed tool is efficacious
- Use is time limited
- o Use is limited geographically
- Use is prescribed/targeted for pathogen/disease of concern

# **Deliberative Process / Ex. 5**

- Application methods are a concern with respect to potential wide scale off-target exposure (e.g., airblast, application until runoff).
  - O Natural sources of water could become exposed to the antimicrobial and spread the exposure.

### **Pending Applications:**

# **Deliberative Process / Ex. 5**

Meeting Minutes: EPA-CDC-FDA teleconference February 10, 2016 — Page 3

Draft 2/25/16 - Finalized 3/16/16

# **Deliberative Process / Ex. 5**

Section 18 – Florida Citrus use

# **Deliberative Process / Ex. 5**

**Action Items** 

# **Deliberative Process / Ex. 5**

Meeting Minutes: EPA-CDC-FDA teleconference February 10, 2016 — Page 4 Draft 2/25/16 - Finalized 3/16/16

# **Deliberative Process / Ex. 5**



### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

PRINCELLOS OFFICERS

### MEMORANDUM

March 30, 2016

Subject:

Emergency Exemption Request for the use of the Antibiotics Streptomycin

sulfate and Oxytetracycline hydrochloride use on Citrus for HLB suppression.

Analysis of resistance risk potential per FDA GF# 152

From:

Karen P. Hicks, Microbiologist (CTT Leader) William For KPH Product Science Branch

Antimicrobials Division (7510P)

John L. Kough, Ph.D., Biologist

Microbial Pesticides Branch, (

Biopesticide and Pollution Prevention Division (7511P)

Through

Shaunta Hill, Ph.D. Plant Pathologist ANUM (241)

Fungicide Branch

Registration Division (RD, 7505P)

To:

Tawanda Maignan, Emergency Response Team Leader

Risk Integration, Minor Use and Emergency Response Branch

Registration Division (RD, 7505P)

**ACTION REQUESTED:** To review information related to the potential use of Streptomycin sulfate and Oxytetracycline hydrochloride on citrus for HLB suppression. This analysis is adapted from the Food and Drug Administration's Center for Veterinary Medicine's Guidance to Industry # 152 which was designed to address the microbial resistance associated with new animal drug uses.

**BACKGROUND:** The qualitative risk assessment as described in the FDA's 152 guidance to industry; with modifications from PRN 2001-5 appropriate to managing resistance in agricultural chemicals, consists of a release assessment, and exposure assessment and a consequence assessment. These three elements provide the information to make an overall qualitative risk estimate. The release assessment considers the probability that resistant bacteria are present on food commodities as a result of antibiotic use on crops. In the case of agricultural use of an antibiotic on a food crop, the primary expression of this resistance would be a failure of the antibiotic to control the intended disease. Another adverse outcome could be the appearance of resistance to the antibiotic in epiphytic or soil bacteria. Either of these scenarios could indicate

an increase in the likelihood of antibiotic resistance transfer to microbes of human health concern and require a closer examination of the resistance trait to determine its mobility among bacterial populations. The exposure assessment considers the probability that humans would ingest or be exposed to bacteria from the treated food commodity. In the case of an agricultural use antibiotic, the incidence of food borne illness associated with consumption of the crop would provide the background for these exposure scenarios.

Another consideration would be increasing exposure to bacteria of human health concern through the use of improperly treated animal manures. The consequence assessment considers the probability that the exposure to resistant bacteria could result in an adverse health consequence. Any change in the incidence of food borne disease found with consumption of the treated crop or an increased failure to treat human disease related to ingesting the crop would be cogent for the consequence assessment.

Given the importance of antibiotics to control bacterial diseases in humans, domestic animals and plants, it is essential that procedures be adopted to lessen the likelihood that antibiotic use in crops leads to selection for resistant bacterial populations. The guidance given in PRN 2001-5 outline general considerations for prudent agricultural use including the avoidance of single chemistry for control, rotating control measures over the season, employing tank mixes to enhance the selection pressure of the sprays used, and basing control strategies on integrated pest management programs. An important first step in any resistance control scheme is to monitor for loss of field efficacy and confirm its source. EPA assumes that loss of field efficacy for the target bacterium, while not the sole indication of antibiotic resistance of importance to bacteria of human health concern, is an important sign that continued agricultural use could affect clinical medicine. EPA also assumes that microbiological impacts conferring cross resistance within the environment could affect clinical medicine.

### ANAYLSIS:

### Streptomycin sulfate; EPA Reg. # 80990-3.

<u>Proposed use summary</u>: The proposed label for the Section 18 permits three applications at 1.35 lbs Al/acre (A)/year. The proposed retreatment interval is 21 days and the pre-harvest interval is 40 days. Per the submitted emergency request, a maximum of 388, 534 acreages of citrus would be treated. This use pattern would result in a release of 524,520.9 lbs of streptomycin sulfate (1.35 lbs x 388,534 acres per year = 524,520.9 lbs) on citrus in Florida for 2016.

Summary of available monitoring data: Available monitoring data for use of streptomycin on grapefruit suggests that there is selection pressure. Where streptomycin sulfate was used; epiphytic bacterial populations resistant to streptomycin sulfate residing on grapefruit leaves increased significantly as compared to untreated control. These bacteria were not identified to provide further details.

### Estimation of Resistance risk:

 Release: "HIGH". Unlike other 152 assessments of streptomycin, recent discussion with FDA and CDC have indicated widespread selection of multidrug resistance plasmids within the Enterobacteriaceae family of bacteria. These bacteria, with plasmid borne resistance, have led to an explosion of infections with carbapenem resistant Enterobacteriaceae (CRE) pathogens recalcitrant to most antibiotic treatments. These plasmids routinely include streptomycin resistance in addition to other classes of antibiotic. Large-scale environmental release (, as envisioned in the Florida citrus section 18 for HLB, would provide abundant selection pressure and favor the increased presence of these multidrug resistance plasmids in CRE as well as other environmental bacteria.

- Exposure: "HIGH". Based on the proposed acreages, airblast application without demonstrated control of the target HLB pathogen, indirect application to target area on trees (e.g., surface treatment without penetration to vascular tissue where bacterium is found).
- Consequence estimation: The estimation is "HIGHLY IMPORTANT". CDC indicated the development and pending approval of plazomicin, a new antibiotic for control of Carbapenem resistant Enterobacteriaceae (e.g., *E.coli, Klebsiella*, and *Salmonella*) could be jeopardized by the larger environmental use of streptomycin. CDC and FDA also indicated there has been increased detection of multidrug resistance plasmids in enteric pathogens such as CRE.
- Overall Risk: "HIGH". This results from a "High" classification for both the release and exposure risk estimates and the "Highly Important" consequence classification.

Recommendation: To reduce the risk potential, the following is recommended.

- Reduced the acreages treated.
- Restrict airblast applications.
- Reduce the number of applications.
- Rotation with copper based pesticides to reduce epiphytic bacteria populations.
- Restrict application in orchards were animal manures are used.
- Restrict applications to natural water sources (streams, creeks, ponds, rivers, and lakes) to minimize run off exposure.

### FireLine 17 WP (Oxytetracycline hydrochloride; EPA Reg. No. 80990-1)

<u>Proposed use summary</u>: The proposed label for the Section 18 permits three applications at 0.81 lbs AI/A/year. The proposed retreatment interval is 21 days and the pre-harvest interval is 40 days. Per the submitted emergency request, a maximum of 388, 534 acreages of citrus would be treated. This use pattern would result in a release of 314,712.54 lbs of oxytetracycline hydrochloride (0.81 lbs x 388,534 acres per year = 314,712.54 lbs) on citrus in Florida for 2016.

<u>Summary of available monitoring data:</u> No monitoring data is available.

### Estimation of Resistance risk:

• Release: "HIGH". Recent discussion with FDA and CDC have indicated that there is an increased occurrence of infections by *Acinetobacter baumanni*, a bacterial pathogen often found in soil and water, whose last line of defense is tetracycline. Use of oxytetracycline in the environment will directly lead to greater selection for tetracycline resistance in

*Acinetobacter* species. Risk includes tetracycline resistance genes ubiquitously found on plasmids carrying resistance to other classes of antimicrobials.

- Exposure: "HIGH". Based on the proposed acreages, airblast application without demonstrated control of the target HLB pathogen, indirect application to target area on trees (e.g., surface treatment without penetration to vascular tissue where bacterium is found).
- Consequence estimation: The estimation is "HIGHLY IMPORTANT". CDC has recently indicated that use of minocycline has provided a last line of treatment for *Acinetobacter* infections. CDC and FDA indicated that minocycline's usefulness could be jeopardized by the larger environmental use of oxytetracycline.
- Overall Risk: "HIGH". This results from a "High" classification for both the release and exposure risk estimates and the "Highly Important" consequence classification.

Recommendation: To reduce the risk potential, the following is recommended.

- Reduced the acreages treated.
- Restrict airblast applications.
- Reduce the number of applications.
- Rotation with copper based pesticides to reduce epiphytic bacteria populations.
- Restrict application in orchards were animal manures are used.
- Restrict applications to natural water sources (streams, creeks, ponds, rivers, and lakes) to minimize run off exposure.
- Restrict applications in the Florida Keys to reduce impacts to ongoing mosquito research.

Note to file: Mycoshield (Oxytetracycline calcium complex; EPA Reg. # 55146-97) is excluded from this assessment due to underlying product chemistry concerns. The registrant has taken steps to correct the issues; however the Agency's assessment is still pending. Per the Product Manager for the product, until the data concerns are fully addressed to support the current Section 3 registration, this product should not be permitted under the current Section 18 request.

From: Hill, Shaunta [Hill.Shaunta@epa.gov]

**Sent**: 2/3/2016 6:47:51 PM

To: Chandgoyal, Tara [Chandgoyal.Tara@epa.gov]

Subject: FW: EPA - Pending antibiotic request for Streptomycin, request for a teleconference

Attachments: image2016-02-01-085505.pdf; 492132-02-XX.PDF

From: Hill, Shaunta

Sent: Monday, February 01, 2016 4:16 PM

**To:** 'Patel, Jean (CDC/OID/NCEZID)' <vzp4@cdc.gov> **Cc:** Jennings, Susan <Jennings.Susan@epa.gov>

Subject: EPA - Pending antibiotic request for Streptomycin, request for a teleconference

Hello Dr. Patel,

First- Happy New Year and I hope all is well.

Second, I wanted to share that EPA is preparing to finalize our 152 assessment for a recent Streptomycin application. The petitioner is seeking foliar use of **streptomycin on grapefruit and tomatoes (greenhouse and field use)**. As we have done with other antibiotics, we would like to hold a teleconference with you to discuss the pending uses and any risk concerns you may have. We have received a letter of permission from the applicant so that we may share the risk assessments with you. Attached are the Agency's 152 review memo and the applicant generated 152 document.

We have availability on <u>Feb 10 (Wed) at 11 am</u> and <u>Feb 11 (Thurs) at 11 am</u>. I am hopefully that one of these options will be suitable for your schedule. If not, please let me know. Additionally we would like to meet with FDA as well. Would you happen to know if David White is still the appropriate contact?

Thank you for your time and I look forward to hearing from you.

### Regards,

\*

Shaunta Hill-Hammond, Ph. D.

Plant Pathologist

U.S. EPA: Office of Chemical Safety and Pollution Prevention

Registration Division/Fungicide Branch (PYS)

1200 Pennsylvania Avenue, NW (7505P)

Washington, DC 20460

Tel: 703.347.8961 1 Fax: 703.305.6920

E-mail: hill.shaunta@epa.gov

URL Address: www.epa.gov/pesticides

From: Maignan, Tawanda [Maignan.Tawanda@epa.gov]

**Sent**: 7/25/2017 6:03:36 PM

**To**: Conrath, Andrea B [Conrath.Andrea@epa.gov]

**Subject**: FW: Federal interagency Antibiotic Resistance Call docs

Attachments: Oxytetracycline 152 Fireline 17WP 07032017.doc; Kasugamin Arysta 152 -07-03-2017.docx; Streptomycin 152

Firewall 50WP 07032017 .doc; Sec 3 grpfrt\_tomato strep 152.pdf

FYI

From: Johnson, Hope

Sent: Tuesday, July 25, 2017 1:54 PM

To: Cain, Tamica <Cain.Tamica@epa.gov>; Maignan, Tawanda <Maignan.Tawanda@epa.gov>

Subject: FW: Federal interagency Antibiotic Resistance Call docs

Hope A. Johnson
Product Manager 21
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division
Fungicide Branch
Phone: 703-305-5410

From: Johnson, Hope

Mail Code 7505P

**Sent:** Thursday, July 20, 2017 10:53 AM

To: Sow, Fatima <<u>Sow.Fatima@epa.gov</u>>; Jennings, Susan <<u>Jennings.Susan@epa.gov</u>>; Kough, John

< Kough. John@epa.gov >; Collins, Samantha < collins. samantha@epa.gov >; Chandgoyal, Tara

<<u>Chandgoyal.Tara@epa.gov</u>>; Garvie, Heather <<u>Garvie.Heather@epa.gov</u>>; Giles-Parker, Cynthia <<u>Giles-</u>

Parker.Cynthia@epa.gov>; 'Carl Schultze' <Carl.P.Schulze@aphis.usda.gov>; Julius Fajardo

<Julius.Fajardo@ARS.USDA.GOV>; 'Heather.Harbottle@fda.hhs.gov' <Heather.Harbottle@fda.hhs.gov>; 'Jean Patel'

<vzp4@cdc.gov>; 'Jeff.Gilbert@fda.hhs.gov' <Jeff.Gilbert@fda.hhs.gov>; 'Michael Craig' <bez7@cdc.gov>; 'Rose

Hammond' <Rose.Hammond@ARS.USDA.GOV>

Cc: 'Cook, Colwell' <cook.colwell@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>; Kaul, Monisha

< Kaul. Monisha@epa.gov>

Subject: RE: Federal interagency Antibiotic Resistance Call

Thank you all again for your participation today on the call. Attached are all the Resistance Review documents for your review in one place. Our BEAD division is determining whether or not we can provide the draft Benefits documents as an FYI. The Benefits documents include discussion on efficacy and alternatives. We will forward those documents to you if we can as soon as possible.

We would appreciate any comments you have- please send as soon as possible and hopefully no later than COB Wednesday 7/26/2017.

Please send any comments to Susan Jennings and cc: myself (Hope Johnson) and Fatima Sow.

Again, please note that we are in the Risk Management stage of the review. In the coming few weeks, we will begin briefings for our Management along with drafting the Proposed Decision documents for each AI (active ingredient) in preparation for the Public Process. We hope to begin the Public Process by the beginning of October of this year. It will

include a 30 day comment period and allows the public to look at all supporting documents associated with the Proposed Decision (Health Effects Division risk assessment, Environmental Fate and Effects Division risk assessment, Biological and Economic Analysis Division Benefits assessment, Resistance Review (former 152), proposed labels). The Proposed Decision will discuss any mitigation we are proposing for that specific Al's new use.

After the comment period has closed, the Agency responds to comments received and incorporates these responses along with any revisions to the Proposed Decision into a Final Decision document. This is then uploaded to the docket, the Registrations are signed, and the Final Rule is published establishing tolerances. We are striving to meet a January 2018 timeframe for the Final Decisions.

Please feel free to contact me if you have questions on the process.

Thank you,

Hope A. Johnson
Product Manager 21
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division
Fungicide Branch
Phone: 703-305-5410
Mail Code 7505P

From: Johnson, Hope

Sent: Thursday, July 20, 2017 8:18 AM

To: Sow, Fatima <<u>Sow.Fatima@epa.gov</u>>; Jennings, Susan <<u>Jennings.Susan@epa.gov</u>>; Kough, John

<Kough.John@epa.gov>; Collins, Samantha <collins.samantha@epa.gov>; Chandgoyal, Tara

<Chandgoyal.Tara@epa.gov>; Garvie, Heather <Garvie.Heather@epa.gov>; Giles-Parker, Cynthia <Giles-</p>

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Cc: Cook, Colwell <cook.colwell@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>

Subject: RE: Federal interagency Antibiotic Resistance Call

The original streptomycin grapefruit/tomato 152 review is attached here. Previously only the addendum was attached. This is the complete document.

Hope A. Johnson
Product Manager 21
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division
Fungicide Branch
Phone: 703-305-5410
Mail Code 7505P

From: Sow, Fatima

**Sent:** Wednesday, July 19, 2017 4:49 PM

**To:** Jennings, Susan <<u>Jennings.Susan@epa.gov</u>>; Kough, John <<u>Kough.John@epa.gov</u>>; Collins, Samantha <<u>collins.samantha@epa.gov</u>>; Chandgoyal, Tara <<u>Chandgoyal.Tara@epa.gov</u>>; Garvie, Heather <<u>Garvie.Heather@epa.gov</u>>; Johnson, Hope <<u>Johnson.Hope@epa.gov</u>>; Giles-Parker, Cynthia <<u>Giles-Parker.Cynthia@epa.gov</u>>; Carl Schultze <<u>Carl.P.Schulze@aphis.usda.gov</u>>; Julius Fajardo

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Jeff.Gilbert@fda.hhs.gov; Michael Craig <bez7@cdc.gov>; Rose Hammond <Rose.Hammond@ARS.USDA.GOV>

**Subject:** RE: Federal interagency Antibiotic Resistance Call

Documents to be discussed are attached.

----Original Appointment----

From: Jennings, Susan

Sent: Monday, June 19, 2017 10:19 AM

**To:** Jennings, Susan; Kough, John; Collins, Samantha; Chandgoyal, Tara; Garvie, Heather; Johnson, Hope; Giles-Parker, Cynthia; Carl Schultze; Julius Fajardo; <a href="mailto:Heather-Harbottle@fda.hhs.gov">Heather-Harbottle@fda.hhs.gov</a>; Jean Patel; <a href="mailto:Jeff.Gilbert@fda.hhs.gov">Jeff.Gilbert@fda.hhs.gov</a>; Michael

Craig; Rose Hammond

Cc: Sow, Fatima

**Subject:** Federal interagency Antibiotic Resistance Call

When: Thursday, July 20, 2017 8:00 AM-10:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: Conference call # 866-299-3188, code 7063558524

Documents to be discussed are attached to this invitation.

This is just a hold until we find a time that works for Federal Partners. Final meeting will be scheduled for 2 hours (but may be shorter).

From: Johnson, Hope [Johnson.Hope@epa.gov]

**Sent**: 7/25/2017 5:55:12 PM

To: Conrath, Andrea B [Conrath.Andrea@epa.gov]

**Subject**: FW: Federal interagency Antibiotic Resistance Call docs

Attachments: Oxytetracycline 152 Fireline 17WP 07032017.doc; Kasugamin Arysta 152 -07-03-2017.docx; Streptomycin 152

Firewall 50WP 07032017 .doc; Sec 3 grpfrt\_tomato strep 152.pdf

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**Sent:** Tuesday, July 25, 2017 1:54 PM

To: Cain, Tamica <Cain.Tamica@epa.gov>; Maignan, Tawanda <Maignan.Tawanda@epa.gov>

Subject: FW: Federal interagency Antibiotic Resistance Call docs

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Mail Code 7505P

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Jeff.Gilbert@fda.hhs.gov; Michael Craig <bez7@cdc.gov>; Rose Hammond <Rose.Hammond@ARS.USDA.GOV>

Subject: RE: Federal interagency Antibiotic Resistance Call

Documents to be discussed are attached.

----Original Appointment----

From: Jennings, Susan

Sent: Monday, June 19, 2017 10:19 AM

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Cc: Sow, Fatima

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From: Patel, Jean (CDC/OID/NCEZID) [vzp4@cdc.gov]

**Sent**: 2/25/2016 7:10:24 PM

To: Wan, Ellen (CDC/OID/NCEZID) [gqj0@cdc.gov]

**CC**: Hill, Shaunta [Hill.Shaunta@epa.gov]

Subject: Fw: Follow-up: Streptomycin and Oxytetracycline pesticide requests pending with EPA

Attachments: Meeting minutes 02102016 EPA-CDC-FDA antibiotics.docx; Mitigation Measures HLB citrus FL.docx; Section 18

citrus 152 review.docx

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: Hill, Shaunta < Hill.Shaunta@epa.gov> Sent: Thursday, February 25, 2016 1:39 PM

To: Patel, Jean (CDC/OID/NCEZID); Craig, Michael R. (CDC/OID/NCEZID); Harbottle, Heather (FDA/CVM); Gilbert,

Jeffrey M (FDA/CVM)

Cc: Jennings, Susan; Kough, John; Chandgoyal, Tara; Hicks, Karen

Subject: Follow-up: Streptomycin and Oxytetracycline pesticide requests pending with EPA

## Good Afternoon Everyone,

Thank you for participating in the teleconference on Feb 10, 2016. As promised, I am following-up with the group to share the draft meeting minutes. I would greatly appreciate your review of the minutes and any comments/corrections you find by 3/3/16.

# **Deliberative Process / Ex. 5**

### The proposed meeting times are:

- Tuesday March 8, 9 am
- Thursday March 10, 1 pm
- Wednesday March 16, 1 pm

Thank you and enjoy the rest of your day.

Regards,

\*

Shaunta Hill-Hammond, Ph. D.

Plant Pathologist

U.S. EPA: Office of Chemical Safety and Pollution Prevention

Registration Division/Fungicide Branch (PYS)

1200 Pennsylvania Avenue, NW (7505P)

Washington, DC 20460

Tel: 703.347.8961 1 Fax: 703.305.6920



From: Wan, Ellen (CDC/OID/NCEZID) [gqj0@cdc.gov]

**Sent**: 2/25/2016 6:53:42 PM

To: Patel, Jean (CDC/OID/NCEZID) [vzp4@cdc.gov]; Hill, Shaunta [Hill.Shaunta@epa.gov]

Subject: RE: Follow-up: Streptomycin and Oxytetracycline pesticide requests pending with EPA

Thank you, Jean, Shaunta. Is there an attachment?

Michael, Jean and I all seem available March 16, 1pm.

From: Patel, Jean (CDC/OID/NCEZID)

Sent: Thursday, February 25, 2016 1:49 PM

To: Wan, Ellen (CDC/OID/NCEZID) <gqj0@cdc.gov>

Cc: Hill, Shaunta < Hill. Shaunta@epa.gov>

Subject: Fw: Follow-up: Streptomycin and Oxytetracycline pesticide requests pending with EPA

Ellen: Pls see below.

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: Hill, Shaunta < Hill. Shaunta@epa.gov > Sent: Thursday, February 25, 2016 1:41 PM

To: Patel, Jean (CDC/OID/NCEZID)

Subject: FW: Follow-up: Streptomycin and Oxytetracycline pesticide requests pending with EPA

Hello Jean,

Unfortunately I could not locate information for Ellen.

Would you mind forwarding my communication to her for input as well.

Thank you for this consideration.

Regards,

Shaunta Hill-Hammond, Ph. D.

Plant Pathologist

U.S. EPA: Office of Chemical Safety and Pollution Prevention

Registration Division/Fungicide Branch (PYS)

1200 Pennsylvania Avenue, NW (7505P)

Washington, DC 20460

Tel: 703.347.8961 1 Fax: 703.305.6920

E-mail: hill.shaunta@epa.gov

From: Hill, Shaunta

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To: Craig, Michael R. (CDC/OID/NCEZID) <a href="mailto:bez7@cdc.gov">bez7@cdc.gov</a>; 'Harbottle, Heather' < Heather, Harbottle@fda.hhs.gov</a>;

Gilbert, Jeffrey M < Jeff. Gilbert@fda.hhs.gov>

Cc: Jennings, Susan < Jennings.Susan@epa.gov>; Kough, John < Kough.John@epa.gov>; Chandgoyal, Tara

Subject: Follow-up: Streptomycin and Oxytetracycline pesticide requests pending with EPA

Good Afternoon Everyone,

Thank you for participating in the teleconference on Feb 10, 2016. As promised, I am following-up with the group to share the draft meeting minutes. I would greatly appreciate your review of the minutes and any comments/corrections you find by 3/3/16.

# **Deliberative Process / Ex. 5**

## The proposed meeting times are:

- Tuesday March 8, 9 am
- Thursday March 10, 1 pm
- Wednesday March 16, 1 pm

Thank you and enjoy the rest of your day.

Regards,

 $\dot{x}$ 

Shaunta Hill-Hammond, Ph. D.
Plant Pathologist
U.S. EPA: Office of Chemical Safety and Pollution Prevention
Registration Division/Fungicide Branch (PYS)
1200 Pennsylvania Avenue, NW (7505P)
Washington, DC 20460

Tel: 703.347.8961 1 Fax: 703.305.6920

E-mail: hill.shaunta@epa.gov

Jean – could you please forward the materials to Ellen.

From: Patel, Jean (CDC/OID/NCEZID) [vzp4@cdc.gov]

**Sent**: 2/1/2016 10:13:13 PM

To: Craig, Michael R. (CDC/OID/NCEZID) [bez7@cdc.gov]

CC: Hill, Shaunta [Hill.Shaunta@epa.gov]; Jennings, Susan [Jennings.Susan@epa.gov]Subject: FW: EPA - Pending antibiotic request for Streptomycin, request for a teleconference

Attachments: image2016-02-01-085505.pdf; 492132-02-XX.PDF

Shaunta and Susan

I am sending to Michael Craig as well to check his availability and to ensure that he has the materials too.

Again, my two follow up questions are:

1. Understanding this request in the context of kasugamycin availability

2. Understanding the extent of this request with the understanding that EPA has already granted emergency use of streptomycin on grapefruit in Florida until July 1, 2016.

From: Hill, Shaunta [mailto:Hill.Shaunta@epa.gov]

Sent: Monday, February 01, 2016 4:18 PM

To: Patel, Jean (CDC/OID/NCEZID) <vzp4@cdc.gov>
Cc: Jennings, Susan <Jennings.Susan@epa.gov>

Subject: EPA - Pending antibiotic request for Streptomycin, request for a teleconference

Hello Dr. Patel,

First- Happy New Year and I hope all is well.

Second, I wanted to share that EPA is preparing to finalize our 152 assessment for a recent Streptomycin application. The petitioner is seeking foliar use of **streptomycin on grapefruit and tomatoes (greenhouse and field use)**. As we have done with other antibiotics, we would like to hold a teleconference with you to discuss the pending uses and any risk concerns you may have. We have received a letter of permission from the applicant so that we may share the risk assessments with you. Attached are the Agency's 152 review memo and the applicant generated 152 document.

We have availability on Feb 10 (Wed) at 11 am and Feb 11 (Thurs) at 11 am. I am hopefully that one of these options will be suitable for your schedule. If not, please let me know. Additionally we would like to meet with FDA as well. Would you happen to know if David White is still the appropriate contact?

Thank you for your time and I look forward to hearing from you.

Regards,

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

Shaunta Hill-Hammond, Ph. D.

Plant Pathologist

U.S. EPA: Office of Chemical Safety and Pollution Prevention

Registration Division/Fungicide Branch (PYS)

1200 Pennsylvania Avenue, NW (7505P) Washington, DC 20460

Tel: 703.347.8961 l Fax: 703.305.6920

E-mail: <u>hill.shaunta@epa.gov</u>

URL Address: www.epa.gov/pesticides

From: Craig, Michael R. (CDC/OID/NCEZID) [bez7@cdc.gov]

**Sent**: 3/11/2016 4:38:00 PM

To: Patel, Jean (CDC/OID/NCEZID) [vzp4@cdc.gov]; Hill, Shaunta [Hill.Shaunta@epa.gov]; Wan, Ellen (CDC/OID/NCEZID)

[gqj0@cdc.gov]

**CC**: Jennings, Susan [Jennings.Susan@epa.gov]

Subject: RE: Follow-up: Streptomycin and Oxytetracycline pesticide requests pending with EPA

For the offices of Ellen and I – you can list Division of Healthcare Quality Promotion

From: Patel, Jean (CDC/OID/NCEZID)
Sent: Thursday, March 10, 2016 1:28 PM

To: Hill, Shaunta <Hill.Shaunta@epa.gov>; Craig, Michael R. (CDC/OID/NCEZID) <bez7@cdc.gov>; Wan, Ellen

(CDC/OID/NCEZID) <gqj0@cdc.gov>

Cc: Jennings, Susan < Jennings.Susan@epa.gov>

Subject: RE: Follow-up: Streptomycin and Oxytetracycline pesticide requests pending with EPA

Attached are CDC's comments on the minutes (unless Michael or Ellen want to add anything).

Thanks,

Jean

From: Hill, Shaunta [mailto:Hill.Shaunta@epa.gov]

Sent: Tuesday, March 08, 2016 2:37 PM

To: Craig, Michael R. (CDC/OID/NCEZID) < bez7@cdc.gov>; Patel, Jean (CDC/OID/NCEZID) < vzp4@cdc.gov>; Wan, Ellen

(CDC/OID/NCEZID) <gqj@cdc.gov>

Cc: Jennings, Susan < Jennings.Susan@epa.gov>

Subject: RE: Follow-up: Streptomycin and Oxytetracycline pesticide requests pending with EPA

HI Michael -

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If its appropriate, we would incorporate similar mitigations for the pending Section 3 (grapefruit and tomato) as proposed for the FL Section 18. Namely:

## **Deliberative Process / Ex. 5**

Of course, if there are other mitigations that CDC would like to apply to the proposed Section 3, we would appreciate that feedback also.

Please let me know if you have additional questions.

Regards,

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

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Sent: Tuesday, March 08, 2016 2:16 PM

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(CDC/OID/NCEZID) <gqi0@cdc.gov>

Cc: Jennings, Susan < Jennings.Susan@epa.gov>

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#### Shaunta:

Thanks for your email. We have been working with Susan and Tawanda on the emergency request from Florida and provided comments to Tawanda yesterday on potential mitigation steps.

Given the developments since our call last month, can you clarify the need for the updated minutes? It seems like some of the issues may now be moot.

Thank you, Michael

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To: Patel, Jean (CDC/OID/NCEZID) < vzp4@cdc.gov>; Craig, Michael R. (CDC/OID/NCEZID) < bez7@cdc.gov>; Wan, Ellen

(CDC/OID/NCEZID) <gaj@cdc.gov>

Subject: RE: Follow-up: Streptomycin and Oxytetracycline pesticide requests pending with EPA

Hello everyone-

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We would greatly appreciate CDC's comments this week if possible.

Thank you

Regards,

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Plant Pathologist

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Washington, DC 20460

Tel: 703.347.8961 1 Fax: 703.305.6920

From: Hill, Shaunta [mailto:Hill.Shaunta@epa.gov]

Sent: Thursday, February 25, 2016 1:38 PM

To: Patel, Jean (CDC); Craig, Michael R (CDC); Harbottle, Heather; Gilbert, Jeffrey M

Cc: Jennings, Susan; Kough, John; Chandgoyal, Tara; Hicks, Karen

Subject: Follow-up: Streptomycin and Oxytetracycline pesticide requests pending with EPA

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Tel: 703.347.8961 1 Fax: 703.305.6920

From: Patel, Jean (CDC/OID/NCEZID) [vzp4@cdc.gov]

**Sent**: 3/10/2016 6:27:45 PM

To: Hill, Shaunta [Hill.Shaunta@epa.gov]; Craig, Michael R. (CDC/OID/NCEZID) [bez7@cdc.gov]; Wan, Ellen

(CDC/OID/NCEZID) [gqj0@cdc.gov]

**CC**: Jennings, Susan [Jennings.Susan@epa.gov]

Subject: RE: Follow-up: Streptomycin and Oxytetracycline pesticide requests pending with EPA

Attachments: Meeting minutes 02102016 EPA-CDC-FDA antibiotics CDC comments.docx

Attached are CDC's comments on the minutes (unless Michael or Ellen want to add anything).

Thanks,

Jean

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Sent: Tuesday, March 08, 2016 2:37 PM

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If its appropriate, we would incorporate similar mitigations for the pending Section 3 (grapefruit and tomato) as proposed for the FL Section 18. Namely:

# **Deliberative Process / Ex. 5**

Of course, if there are other mitigations that CDC would like to apply to the proposed Section 3, we would appreciate that feedback also.

Please let me know if you have additional questions.

Regards,

\*

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(CDC/OID/NCEZID) <gaj@cdc.gov>

Cc: Jennings, Susan < Jennings. Susan@epa.gov>

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#### Shaunta:

Thanks for your email. We have been working with Susan and Tawanda on the emergency request from Florida and provided comments to Tawanda yesterday on potential mitigation steps.

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(CDC/OID/NCEZID) <ggi@cdc.gov>

Subject: RE: Follow-up: Streptomycin and Oxytetracycline pesticide requests pending with EPA

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\*

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Washington, DC 20460

Tel: 703.347.8961 1 Fax: 703.305.6920

E-mail: hill.shaunta@epa.gov

From: Hill, Shaunta [mailto:Hill.Shaunta@epa.gov]

**Sent:** Thursday, February 25, 2016 1:38 PM

To: Patel, Jean (CDC); Craig, Michael R (CDC); Harbottle, Heather; Gilbert, Jeffrey M

Cc: Jennings, Susan; Kough, John; Chandgoyal, Tara; Hicks, Karen

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Washington, DC 20460

Tel: 703.347.8961 1 Fax: 703.305.6920

#### EPA - FDA - CDC Teleconference Feb 10, 2016.

**DRAFT Meeting Minutes** 

#### Meeting Participants:

| wiceding 1 articipants.   |
|---|
| EPA – Office of Pesticide Programs  |
| Shaunta Hill, PhD. Plant Pathologist  |
| Fungicide Branch, Registration Division   |
| Karen P. Hicks, Microbiologist, CTT Lead  |
| Product Science Branch, Antimicrobials Division                                 |
| John L. Kough, Ph.D., Biologist   |
| Microbial Pesticides Branch,  |
| Biopesticide and Pollution Prevention Division                                  |
| Tara Chandgoyal, Ph.D, Plant Pathologist  |
| Biological Assessment Branch, Biological, Economical, Assessment Division       |
| Susan Jennings, Public Health Coordinator                                       |
| Immediate Office, Registration Division   |
| CDC - National Center for Emerging and Zoonotic Infectious Diseases             |
| Jean Patel, Ph.D. Deputy Director,  |
| Office of Antimicrobial Resistance, Division of Healthcare Quality Promotion    |
| Michael Craig, MPP Program Analyst  |
| Office of   |
| Ellen Wan, Public Health Analyst  |
| Office of   |
| FDA - Office of New Animal Drug Evaluation, Center for Veterinary Medicine, FDA |
| Jeff Gilbert, Ph.D. Microbiologist, Team Leader                                 |
| Microbial Food Safety Team  |
| Heather Harbottle, Ph.D. Microbiologist,  |
| Microbial Food Safety Team  |
| Meeting Observers:  |
| EPA - Fungicide Branch, Registration Division                                   |
| Fatima Sow  |
| Hope Johnson, PM 21   |
| Cynthia Giles-Parker, Branch Chief  |
| EPA - Pesticide Re-evaluation Division  |
| Cathryn Britton   |
| Matthew Manupella   |

Summary: The Office of Pesticide Programs of the U.S. Environmental Protection Agency held a teleconference with CDC and FDA to discuss pesticide application requests for the antibiotics streptomycin and oxytetracycline. The teleconference was held on February 10, 2016. CDC and FDA participants shared several general points with respect to pesticidal use of streptomycin and oxytetracycline, including new resistance concerns and new drug development. With respect to the pending pesticide applications, EPA shared the proposed risk classification for the grapefruit /tomato Section 3 request. EPA highlighted the application details for the proposed Section 18 request and noted the full assessment was pending. Details of the discussion are listed below.

Meeting Minutes: EPA-CDC-FDA teleconference February 10, 2016 - Page [ PAGE \\* MERGEFORMAT 1

Draft 2/25/16

#### General points of the discussion:

- EPA shared that the current applications reference "low usage" comparative to current human or animal use.
  - CDC/FDA: Although pesticidal uses are lower than therapeutic use, resistance risk is not removed.
    - Low residue concentrations can select for resistance.
    - There is a better appreciation for resistance development as diagnostic tools have evolved to detect these traits in bacterial populations.
- CDC: New aminoglycosides (plazomicin) are in development. Older tetracyclines (minocycline) are finding use against newly emerging bacterial diseases. Additional pesticidal use of drugs currently used in human medicine could jeopardize the effectiveness of the new tools given increased detection in plasmid mediated transfers.
  - There is an increased occurrence of infections by Acinetobacter baumanni, a
    bacterial pathogen often found in soil and water, whose last line of defense is
    tetracycline. Use of oxytetracycline in the environment will directly lead to
    greater selection for tetracycline resistance in Acinetobacter species.
  - o There is widespread selection of multidrug resistance plasmids within the Enterobacteriaceae family of bacteria. These bacteria, with plasmid borne resistance, have led to an explosion of infections with carbapenem resistant Enterobacteriaceae (CRE) pathogens recalcitrant to most antibiotic treatments. These plasmids routinely include streptomycin resistance in addition to other classes of antibiotic. Large-scale environmental release, as envisioned in the Florida citrus Section 18 for HLB, would provide abundant selection pressure and favor the increased presence of these multidrug resistance plasmids in CRE as well as other environmental bacteria.
- FDA is proceeding with efforts to increase judicious use of antibiotics. This means that unnecessary or inappropriate use of antibiotics will be avoided. The framework includes the principles of phasing in such measures as 1) limiting medically important antimicrobial drugs to uses in food-producing animals that are considered necessary for assuring animal health; and 2) limiting such drugs to uses in food-producing animals that include veterinary oversight or consultation. Developing strategies for reducing antimicrobial resistance is critically important for protecting both public and animal health. Reference documents include:
  - o GF #209: The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals (FDA notes this is the **Policy** document)
  - GF# 213: New Animal Drugs and New Animal Drug Combination Products
     Administered in or on Medicated Feed or Drinking Water of Food Producing
     Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product
     Use Conditions with GFI #209 (FDA notes this is the Implementation document)
- CDC would recommend Section 18 antibiotic use over Section 3 use where:
  - o No good alternatives are available
  - o Monitoring data is required

Meeting Minutes: EPA-CDC-FDA teleconference February 10, 2016 - Page [ PAGE \\* MERGEFORMAT ]
Draft 2/25/16

### **Deliberative Process / Ex. 5**

**Deliberative Process / Ex. 5** 

Pending Applications:

## **Deliberative Process / Ex. 5**

Meeting Minutes: EPA-CDC-FDA teleconference February 10, 2016  $\,-\,$  Page [ PAGE  $\,$  \* MERGEFORMAT ] Draft 2/25/16

## **Deliberative Process / Ex. 5**

**Action Items** 

**Deliberative Process / Ex. 5** 

From: Hill, Shaunta [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=80C44B96421D4D83A7238F4A0C0C9A39-SHAUNTA HILL]

**Sent**: 3/8/2016 7:36:43 PM

To: Craig, Michael R. (CDC/OID/NCEZID) [bez7@cdc.gov]; Patel, Jean (CDC/OID/NCEZID) [vzp4@cdc.gov]; Wan, Ellen

(CDC/OID/NCEZID) [gqj0@cdc.gov]

CC: Jennings, Susan [Jennings.Susan@epa.gov]

Subject: RE: Follow-up: Streptomycin and Oxytetracycline pesticide requests pending with EPA

Attachments: Meeting minutes 02102016 EPA-CDC-FDA antibiotics.docx

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Please let me know if you have additional questions.

#### Regards,

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E-mail: hill.shaunta@epa.gov

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To: Hill, Shaunta <Hill.Shaunta@epa.gov>; Patel, Jean (CDC/OID/NCEZID) <vzp4@cdc.gov>; Wan, Ellen

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Tel: 703.347.8961 1 Fax: 703.305.6920

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(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=80C44B96421D4D83A7238F4A0C0C9A39-SHAUNTA HILL]

**Sent**: 3/2/2016 5:32:50 PM

To: Craig, Michael R. (CDC/OID/NCEZID) [bez7@cdc.gov]; Patel, Jean (CDC/OID/NCEZID) [vzp4@cdc.gov]; Wan, Ellen

(CDC/OID/NCEZID) [gqj0@cdc.gov]; Harbottle, Heather (FDA/CVM) [Heather.Harbottle@fda.hhs.gov]; Gilbert,

Jeffrey M (FDA/CVM) [Jeff.Gilbert@fda.hhs.gov]

**CC**: Jennings, Susan [Jennings.Susan@epa.gov]

Subject: RE: Follow-up: Streptomycin and Oxytetracycline pesticide requests pending with EPA

Thank you Michael.

It seems that we have a consensus for March 16, 2016 at 1 pm.

We should have the agenda/teleconference information available next week.

In meantime – if there are any questions, comments on the proposed citrus use in FL/152 review + proposed mitigations; I'm happy to receive those today.

We are expecting a call from FL this afternoon and can use that as an opportunity to obtain additional information from ahead of our next teleconference.

Thanks Shaunta

From: Craig, Michael R. (CDC/OID/NCEZID) [mailto:bez7@cdc.gov]

Sent: Wednesday, March 02, 2016 12:13 PM

**To:** Patel, Jean (CDC/OID/NCEZID) <vzp4@cdc.gov>; Hill, Shaunta <Hill.Shaunta@epa.gov>; Harbottle, Heather (FDA/CVM) <Heather.Harbottle@fda.hhs.gov>; Gilbert, Jeffrey M (FDA/CVM) <Jeff.Gilbert@fda.hhs.gov>

**Subject:** RE: Follow-up: Streptomycin and Oxytetracycline pesticide requests pending with EPA

Yes, 16th works for me.

From: Patel, Jean (CDC/OID/NCEZID)

Sent: Wednesday, March 02, 2016 12:11 PM

To: Hill, Shaunta < Hill. Shaunta@epa.gov>; Harbottle, Heather (FDA/CVM) < Heather. Harbottle@fda.hhs.gov>; Craig,

Michael R. (CDC/OID/NCEZID) <a href="mailto:sep://www.ncezin.com/colored-berg-michael-ncezin.com/berg-michael-ncezin.com/colored-berg-michael-ncezin.com/color

Subject: RE: Follow-up: Streptomycin and Oxytetracycline pesticide requests pending with EPA

Shaunta

Could I please send comments/edits on the notes by Monday, March 6<sup>th</sup>. I will send in the am.

Also, March 16th works best for me. I think for Michael as well, but will let him respond if not.

Thanks,

Jean

From: Hill, Shaunta [mailto:Hill.Shaunta@epa.gov]

Sent: Tuesday, March 01, 2016 4:22 PM

To: Harbottle, Heather (FDA/CVM) < Heather. Harbottle@fda.hhs.gov>; Patel, Jean (CDC/OID/NCEZID) < vzp4@cdc.gov>;

Craig, Michael R. (CDC/OID/NCEZID) < bez7@cdc.gov>; Gilbert, Jeffrey M (FDA/CVM) < Jeff.Gilbert@fda.hhs.gov>

Subject: RE: Follow-up: Streptomycin and Oxytetracycline pesticide requests pending with EPA

Hello everyone,

That comment is relative to EPA's request for a written position from CDC and FDA that we could share with management.

# **Deliberative Process / Ex. 5**

Notes from the meeting:

### **Deliberative Process / Ex. 5**

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

2. FDA's position to encourage judicious use of the

antibiotics; 3. Increased detection of resistance mediated plasmids; etc.

Please let me know if you have additional questions.

Regards,

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Plant Pathologist

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Registration Division/Fungicide Branch (PYS)

1200 Pennsylvania Avenue, NW (7505P)

Washington, DC 20460

Tel: 703.347.8961 1 Fax: 703.305.6920

E-mail: hill.shaunta@epa.gov

From: Harbottle, Heather [mailto:Heather.Harbottle@fda.hhs.gov]

Sent: Tuesday, March 01, 2016 10:40 AM

To: Hill, Shaunta < Hill. Shaunta@epa.gov>; Patel, Jean (CDC) < vzp4@cdc.gov>; Craig, Michael R (CDC) < bez7@cdc.gov>;

Gilbert, Jeffrey M < Jeff. Gilbert@fda.hhs.gov>

Subject: RE: Follow-up: Streptomycin and Oxytetracycline pesticide requests pending with EPA

Good Morning Shaunta, Jean, and Michael,

I've been reading over the minutes that Shaunta sent out and making comments to send back for inclusion. I noticed that there's a line item for FDA and CDC and wondered if I could get some clarification.

"CDC and FDA jointly will provide:

Position statement on the use of streptomycin as a pesticide"

Could you please clarify what you'd like us to send? Jean, Michael, have you yet addressed this?

Thanks,

Heather

From: Hill, Shaunta [mailto:Hill.Shaunta@epa.gov]

Sent: Thursday, February 25, 2016 1:38 PM

To: Patel, Jean (CDC); Craig, Michael R (CDC); Harbottle, Heather; Gilbert, Jeffrey M

Cc: Jennings, Susan; Kough, John; Chandgoyal, Tara; Hicks, Karen

Subject: Follow-up: Streptomycin and Oxytetracycline pesticide requests pending with EPA

Good Afternoon Everyone,

Thank you for participating in the teleconference on Feb 10, 2016. As promised, I am following-up with the group to share the draft meeting minutes. I would greatly appreciate your review of the minutes and any comments/corrections you find by 3/3/16.

# **Deliberative Process / Ex. 5**

### The proposed meeting times are:

- Tuesday March 8, 9 am
- Thursday March 10, 1 pm
- Wednesday March 16, 1 pm

Thank you and enjoy the rest of your day.

Regards,

\*

Shaunta Hill-Hammond, Ph. D.
Plant Pathologist
U.S. EPA: Office of Chemical Safety and Pollution Prevention
Registration Division/Fungicide Branch (PYS)
1200 Pennsylvania Avenue, NW (7505P)
Washington, DC 20460

Tel: 703.347.8961 1 Fax: 703.305.6920

E-mail: hill.shaunta@epa.gov

Jean – could you please forward the materials to Ellen.



From: Hill, Shaunta [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=80C44B96421D4D83A7238F4A0C0C9A39-SHAUNTA HILL]

**Sent**: 2/3/2016 5:13:49 PM

To: Patel, Jean (CDC/OID/NCEZID) [vzp4@cdc.gov]; Craig, Michael R. (CDC/OID/NCEZID) [bez7@cdc.gov]

**CC**: Jennings, Susan [Jennings.Susan@epa.gov]

Subject: EPA: Streptomycin and Oxytetracycline - Section 18 citrus request for HLB

Attachments: FDA 152, FireLine Resistance Risk Assessment, 10-2-15.pdf; FDA 152 FireWall Resistance Risk Assessment HLB and

Canker 10-19-15.pdf; FL Citrus Greening Section 18 Antimicrobial Request petition and letter.pdf; 152 NuFarm

MycoShield Oxytet complete.pdf

### Hello everyone,

Per my communication earlier today; attached are additional 152 reports for new Section 18 requests.

FL is seeking Streptomycin and Oxytetracycline use for citrus to manage HLB or Citrus Greening. In addition to the 152 document, I am providing the request petition which provides details of the request and HLB.

EPA is evaluating these submissions. However, if there is time next week, we would like to gather inputs for these requests as well.

Thank you

From: Hill, Shaunta [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=80C44B96421D4D83A7238F4A0C0C9A39-SHAUNTA HILL]

**Sent**: 3/2/2016 5:14:23 PM

To: Patel, Jean (CDC/OID/NCEZID) [vzp4@cdc.gov]; Harbottle, Heather (FDA/CVM) [Heather.Harbottle@fda.hhs.gov];

Craig, Michael R. (CDC/OID/NCEZID) [bez7@cdc.gov]; Gilbert, Jeffrey M (FDA/CVM) [Jeff.Gilbert@fda.hhs.gov]

Subject: RE: Follow-up: Streptomycin and Oxytetracycline pesticide requests pending with EPA

Hello Jean,

Your comments by Monday morning will be fine.

Thank you -Shaunta

From: Patel, Jean (CDC/OID/NCEZID) [mailto:vzp4@cdc.gov]

Sent: Wednesday, March 02, 2016 12:11 PM

To: Hill, Shaunta < Hill. Shaunta@epa.gov>; Harbottle, Heather (FDA/CVM) < Heather. Harbottle@fda.hhs.gov>; Craig,

Michael R. (CDC/OID/NCEZID) <bez7@cdc.gov>; Gilbert, Jeffrey M (FDA/CVM) <Jeff.Gilbert@fda.hhs.gov>

Subject: RE: Follow-up: Streptomycin and Oxytetracycline pesticide requests pending with EPA

Shaunta

Could I please send comments/edits on the notes by Monday, March 6<sup>th</sup>. I will send in the am.

Also, March 16<sup>th</sup> works best for me. I think for Michael as well, but will let him respond if not.

Thanks,

Jean

From: Hill, Shaunta [mailto:Hill.Shaunta@epa.gov]

Sent: Tuesday, March 01, 2016 4:22 PM

**To:** Harbottle, Heather (FDA/CVM) < <u>Heather.Harbottle@fda.hhs.gov</u>>; Patel, Jean (CDC/OID/NCEZID) < <u>vzp4@cdc.gov</u>>; Craig, Michael R. (CDC/OID/NCEZID) < <u>bez7@cdc.gov</u>>; Gilbert, Jeffrey M (FDA/CVM) < <u>Jeff.Gilbert@fda.hhs.gov</u>>

**Subject:** RE: Follow-up: Streptomycin and Oxytetracycline pesticide requests pending with EPA

Hello everyone,

That comment is relative to EPA's request for a written position from CDC and FDA that we could share with management.

# **Deliberative Process / Ex. 5**

Notes from the meeting:

### **Deliberative Process / Ex. 5**

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

2. FDA's position to encourage judicious use of the

antibiotics; 3. Increased detection of resistance mediated plasmids; etc.

Please let me know if you have additional questions.

Regards,

Shaunta Hill-Hammond, Ph. D.

Plant Pathologist

U.S. EPA: Office of Chemical Safety and Pollution Prevention

Registration Division/Fungicide Branch (PYS)

1200 Pennsylvania Avenue, NW (7505P)

Washington, DC 20460

Tel: 703.347.8961 1 Fax: 703.305.6920

E-mail: hill.shaunta@epa.gov

From: Harbottle, Heather [mailto:Heather.Harbottle@fda.hhs.gov]

Sent: Tuesday, March 01, 2016 10:40 AM

To: Hill, Shaunta < Hill. Shaunta@epa.gov>; Patel, Jean (CDC) < vzp4@cdc.gov>; Craig, Michael R (CDC) < bez7@cdc.gov>;

Gilbert, Jeffrey M < Jeff. Gilbert@fda.hhs.gov>

Subject: RE: Follow-up: Streptomycin and Oxytetracycline pesticide requests pending with EPA

Good Morning Shaunta, Jean, and Michael,

I've been reading over the minutes that Shaunta sent out and making comments to send back for inclusion. I noticed that there's a line item for FDA and CDC and wondered if I could get some clarification.

"CDC and FDA jointly will provide:

1. Position statement on the use of streptomycin as a pesticide"

Could you please clarify what you'd like us to send? Jean, Michael, have you yet addressed this?

Thanks, Heather

From: Hill, Shaunta [mailto:Hill.Shaunta@epa.gov]

Sent: Thursday, February 25, 2016 1:38 PM

To: Patel, Jean (CDC); Craig, Michael R (CDC); Harbottle, Heather; Gilbert, Jeffrey M

**Cc:** Jennings, Susan; Kough, John; Chandgoyal, Tara; Hicks, Karen

Subject: Follow-up: Streptomycin and Oxytetracycline pesticide requests pending with EPA

Good Afternoon Everyone,

Thank you for participating in the teleconference on Feb 10, 2016. As promised, I am following-up with the group to share the draft meeting minutes. I would greatly appreciate your review of the minutes and any comments/corrections you find by 3/3/16.

# **Deliberative Process / Ex. 5**

# **Deliberative Process / Ex. 5**

### The proposed meeting times are:

- Tuesday March 8, 9 am
- Thursday March 10, 1 pm
- Wednesday March 16, 1 pm

Thank you and enjoy the rest of your day.

Regards,

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

Shaunta Hill-Hammond, Ph. D.

Plant Pathologist

U.S. EPA: Office of Chemical Safety and Pollution Prevention

Registration Division/Fungicide Branch (PYS)

1200 Pennsylvania Avenue, NW (7505P)

Washington, DC 20460

Tel: 703.347.8961 1 Fax: 703.305.6920

E-mail: hill.shaunta@epa.gov

Jean – could you please forward the materials to Ellen.

From: Hill, Shaunta [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=80C44B96421D4D83A7238F4A0C0C9A39-SHAUNTA HILL]

**Sent**: 2/8/2016 9:11:18 PM

To: Patel, Jean (CDC/OID/NCEZID) [vzp4@cdc.gov]; Craig, Michael R. (CDC/OID/NCEZID) [bez7@cdc.gov]

**CC**: Jennings, Susan [Jennings.Susan@epa.gov]

**Subject**: Streptomycin teleconference - Agenda and support files #2

Attachments: 6. FL Citrus Greening Section 18 Antimicrobial Request petition and letter.pdf; 7. FDA 152 FireWall Resistance Risk

Assessment HLB and Canker 10-19-15.pdf; 8. FDA 152, FireLine Resistance Risk Assessment, 10-2-15.pdf

This is the second email for Wednesday's teleconference. If you have any questions / trouble with the files, please let me know. Thank you

Regards,

\*

Shaunta Hill-Hammond, Ph. D.

Plant Pathologist

U.S. EPA: Office of Chemical Safety and Pollution Prevention

Registration Division/Fungicide Branch (PYS)

1200 Pennsylvania Avenue, NW (7505P)

Washington, DC 20460

Tel: 703.347.8961 l Fax: 703.305.6920

E-mail: hill.shaunta@epa.gov

URL Address: www.epa.gov/pesticides

From: Hill, Shaunta [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=80C44B96421D4D83A7238F4A0C0C9A39-SHAUNTA HILL]

**Sent**: 2/8/2016 9:08:40 PM

To: Patel, Jean (CDC/OID/NCEZID) [vzp4@cdc.gov]; Craig, Michael R. (CDC/OID/NCEZID) [bez7@cdc.gov]

**CC**: Jennings, Susan [Jennings.Susan@epa.gov]

**Subject**: Streptomycin teleconference - Agenda and support files

Attachments: 1. Resistance Monitoring Protocol Draft 11-13-14.pdf; 2. 2014 Testing and Field Monitoring for Streptomycin

Resistance under FL sec18-2015-May29.pdf; 3. 4921332-02-XX.PDF; 4. image2016-02-01-085505.pdf; 5. 080990-

00003.20151123.revised Master Label.pdf; Meeting agenda.pdf

### Good afternoon everyone,

Please see the attached agenda and support files for our teleconference on Wednesday – Feb 10, 2016.

The conference line information is noted on the agenda.

\*Due to the file sizes, two emails will be sent.

From: Hill, Shaunta [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=80C44B96421D4D83A7238F4A0C0C9A39-SHAUNTA HILL]

**Sent**: 2/3/2016 3:11:52 PM

**To**: Patel, Jean (CDC/OID/NCEZID) [vzp4@cdc.gov]

CC: Jennings, Susan [Jennings.Susan@epa.gov]; Craig, Michael R. (CDC/OID/NCEZID) [bez7@cdc.gov]

Subject: RE: EPA - Pending antibiotic request for Streptomycin, request for a teleconference

Attachments: 2014 Testing and Field Monitoring for Streptomycin Resistance under FL sec18-2015-May29.pdf; Resistance

Monitoring Protocol Draft 11-13-14.pdf

### Good Morning Jean,

I have provided a table below indicating the section 18 and section 3 approvals over the last couple of years.

| Crop        | Pest             | State   | Status    | Received | Response | Expiration | FIFRA   |
|-------------|------------------|---------|-----------|----------|----------|------------|---------|
|             |                  |         |           |          |          | Date       | Section |
| Grapefruit  | Citrus<br>canker | Florida | Withdrawn | 9/21/11  | 10/27/11 | -          | 18      |
| Grapefruit  | Citrus<br>canker | Florida | Withdrawn | 1/5/12   | 4/25/12  | -          | 18      |
| Grapefruit  | Citrus<br>canker | Florida | Issued    | 5/7/12   | 9/14/12` | 9/1/13     | 18      |
| Grapefruit  | Citrus<br>canker | Florida | Issued    | 2/12/14  | 6/12/14  | 6/12/15    | 18      |
| Grapefruit  | Citrus<br>canker | Florida | Issued    | 1/29/15  | 7/1/15   | 7/1/16     | 18      |
| Kasugamycin | Pome<br>fruit    | -       | -         | -        | -        | 12/31/18   | 3       |

Kasugamycin is registered for pome use only. Streptomycin was requested and issued via Section 18 for citrus canker on grapefruit. We have received 1 monitoring report (reflective of the 2014 season). Needless to say, FL will need additional guidance on their monitoring protocol and reporting. I have attached the report and protocol for your reference and would welcome your comments also.

The pending requests –now under section 3 are for streptomycin use on grapefruit (limited to Florida) and tomatoes in both greenhouse and field settings.

The Agency is also in receipt of NEW Section 18 **and** Section 3 requests for the citrus crop group (oranges, lemon and grapefruit) for control/therapeutic management of Huanglongbing (aka Citrus Greening or HLB). These requests include streptomycin and oxytetracycline calcium/ oxytetracycline hydrochloride.

For our discussion next week, we would like to focus on the pending Section 3 registration request for Streptomycin on grapefruit and tomatoes.

# **Deliberative Process / Ex. 5**

If you have additional questions, please let me know.

### Regards,

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

Shaunta Hill-Hammond, Ph. D.

Plant Pathologist

U.S. EPA: Office of Chemical Safety and Pollution Prevention

Registration Division/Fungicide Branch (PYS)

1200 Pennsylvania Avenue, NW (7505P)

Washington, DC 20460

Tel: 703.347.8961 1 Fax: 703.305.6920

E-mail: hill.shaunta@epa.gov

URL Address: <a href="https://www.epa.gov/pesticides">www.epa.gov/pesticides</a>

From: Patel, Jean (CDC/OID/NCEZID) [mailto:vzp4@cdc.gov]

**Sent:** Tuesday, February 02, 2016 8:32 AM **To:** Hill, Shaunta < Hill.Shaunta@epa.gov>

Subject: RE: EPA - Pending antibiotic request for Streptomycin, request for a teleconference

Thanks. This is helpful. Could you please remind me of the history of kasugamycin for preventing grapefruit canker? It

## Deliberative Process / Ex. 5

Did the request for streptomycin section 3 approval come from the FL Dept of Agriculture?

I don't want to argue all of these points by email, but I am unclear what the scope of the discussion will be next week so I'm trying to prepare.

Thanks,

Jean

From: Hill, Shaunta [mailto:Hill.Shaunta@epa.gov]

Sent: Tuesday, February 02, 2016 6:48 AM

**To:** Patel, Jean (CDC/OID/NCEZID) < vzp4@cdc.gov > **Cc:** Jennings, Susan < Jennings, Susan@epa.gov >

Subject: RE: EPA - Pending antibiotic request for Streptomycin, request for a teleconference

Hello Jean,

The current grapefruit streptomycin approval is for Section 18 use in FL. The state must request the use on a yearly basis.

The pending request is for a full registration under Section 3.

| Although kasugamycin was requested for pome fruit, walnuts and fruiting vegetab | les; |
|---|------|
| registration was only granted for pome fruit. Deliberative Process / Ex. 5      |      |
| Deliberative Process / Ex. 5  |      |
| Deliberative Process / Ex. 5  |      |

-Shaunta

From: Patel, Jean (CDC/OID/NCEZID) [mailto:vzp4@cdc.gov]

Sent: Monday, February 01, 2016 4:28 PM
To: Hill, Shaunta < Hill. Shaunta@epa.gov >
Cc: Jennings, Susan < Jennings, Susan@epa.gov >

Subject: RE: EPA - Pending antibiotic request for Streptomycin, request for a teleconference

Susan or Shaunta:

Can you please tell me why Streptomycin is being requested here when Kasugamyicin is already available? Also who else will be on this call?

Deliberative Process / Ex. 5

Jean

From: Hill, Shaunta [mailto:Hill.Shaunta@epa.gov]

Sent: Monday, February 01, 2016 4:18 PM

**To:** Patel, Jean (CDC/OID/NCEZID) < vzp4@cdc.gov > **Cc:** Jennings, Susan < Jennings, Susan@epa.gov >

Subject: EPA - Pending antibiotic request for Streptomycin, request for a teleconference

Hello Dr. Patel,

First- Happy New Year and I hope all is well.

Second, I wanted to share that EPA is preparing to finalize our 152 assessment for a recent Streptomycin application. The petitioner is seeking foliar use of **streptomycin on grapefruit and tomatoes (greenhouse and field use)**. As we have done with other antibiotics, we would like to hold a teleconference with you to discuss the pending uses and any risk concerns you may have. We have received a letter of permission from the applicant so that we may share the risk assessments with you. Attached are the Agency's 152 review memo and the applicant generated 152 document.

We have availability on Feb 10 (Wed) at 11 am and Feb 11 (Thurs) at 11 am. I am hopefully that one of these options will be suitable for your schedule. If not, please let me know. Additionally we would like to meet with FDA as well. Would you happen to know if David White is still the appropriate contact?

Thank you for your time and I look forward to hearing from you.

Regards,

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

Shaunta Hill-Hammond, Ph. D.

Plant Pathologist

U.S. EPA: Office of Chemical Safety and Pollution Prevention

Registration Division/Fungicide Branch (PYS)

1200 Pennsylvania Avenue, NW (7505P)

Washington, DC 20460

Tel: 703.347.8961 l Fax: 703.305.6920

E-mail: hill.shaunta@epa.gov

URL Address: www.epa.gov/pesticides

### Appointment

From: Patel, Jean (CDC/OID/NCEZID) [vzp4@cdc.gov]

**Sent**: 9/5/2018 12:57:03 PM

To: Patel, Jean (CDC/OID/NCEZID) [vzp4@cdc.gov]; Craig, Michael R. (CDC/OID/NCEZID) [bez7@cdc.gov]; Pantino,

Elizabeth (CDC/OID/NCEZID) [ymt0@cdc.gov]; Jennings, Susan [Jennings.Susan@epa.gov]

**Subject**: Resolving the EPA comments

Attachments: AMR Env Forum Report combined\_083118 EPA Pesticide Comments.docx

**Location**: Teleconference

**Start**: 9/6/2018 5:00:00 PM **End**: 9/6/2018 6:00:00 PM

Show Time As: Tentative

Recurrence: (none)

Susan – please forward to Mike.

USA Conference Line/Code / Ex. 6

Leader Passcode: 2 Conference Lin

From: Patel, Jean (CDC/DDID/NCEZID/DHQP) [vzp4@cdc.gov]

**Sent**: 11/15/2018 10:19:41 PM

To: Jennings, Susan [Jennings.Susan@epa.gov]

CC: Suarez, Mark [Suarez.Mark@epa.gov]; Thaker, Kaytna (CDC/DDID/NCEZID/DHQP) (CTR) [xxb4@cdc.gov]

**Subject**: RE: Most recent AR in the environment draft

Attachments: AMR Env Forum Report combined 11012018 MS JBP.docx

Please see responses to Mark's comments and proposed edits. I hope this helps. Can you let me know if these changes suffice? If not, let's arrange a quick call tomorrow.

Thanks,

Jean

From: Jennings, Susan < Jennings.Susan@epa.gov> Sent: Wednesday, November 14, 2018 9:04 AM

To: Patel, Jean (CDC/DDID/NCEZID/DHQP) <vzp4@cdc.gov>

Cc: Suarez, Mark <Suarez.Mark@epa.gov>

Subject: FW: Most recent AR in the environment draft

Jean,

See the attached comments, particularly on the usage section, from Mark.

Thanks,

Susan.

From: Suarez, Mark

Sent: Tuesday, November 13, 2018 6:00 PM
To: Jennings, Susan < Jennings.Susan@epa.gov >
Subject: RE: Most recent AR in the environment draft

### **Deliberative Process / Ex. 5**

I have other comments, as well. See attached.

Let me know, if you'd like to discuss it.

Regards, Mark

Mark Suarez
Entomologist
Science Information and Analysis Branch
Biological and Economic Analysis Division
US EPA (Mail Code 7503P)
1200 Pennsylvania Avenue, NW
Washington, DC 20460

phone: 703-305-0120

From: Jennings, Susan

**Sent:** Tuesday, November 13, 2018 12:19 PM **To:** Suarez, Mark < Suarez. Mark@epa.gov>

Subject: Re: Most recent AR in the environment draft

Maybe just check that they made your earlier comments?

On Nov 13, 2018, at 12:17 PM, Suarez, Mark <<u>Suarez.Mark@epa.gov</u>> wrote:

Susan,

I did want to give another once through. I'll make comments by COB.

Regards, Mark

Mark Suarez
Entomologist
Science Information and Analysis Branch
Biological and Economic Analysis Division
US EPA (Mail Code 7503P)
1200 Pennsylvania Avenue, NW
Washington, DC 20460

phone: 703-305-0120

From: Jennings, Susan

**Sent:** Tuesday, November 13, 2018 11:31 AM **To:** Suarez, Mark < Suarez Mark@epa.gov >

Subject: Most recent AR in the environment draft

Hi Mark,

Are you planning to comment on this most recent version? If you haven't looked into it yet, I wouldn't worry about it. I skimmed it and it looked ok.

Thanks,

SUsan.

From: Patel, Jean (CDC/DDID/NCEZID) [vzp4@cdc.gov]

**Sent**: 11/8/2018 7:48:27 PM

To: Jennings, Susan [Jennings.Susan@epa.gov]
Subject: FW: response to remaining EPA comments

Attachments: AMR Env Forum Report combined\_083118 EPA Pesticide Comments.docx; Inernational Environmental AMR Forum

Edits since Aug 31.docx

Susan

Attached is the version I sent on 8/31 – I think this is the last version you saw.

Then, I have the current version that shows all changes done since as track changes.

I hope this helps.

Jean

From: Patel, Jean (CDC/OID/NCEZID)

**Sent:** Wednesday, September 5, 2018 8:51 AM **To:** 'Jennings, Susan' < Jennings.Susan@epa.gov>

Cc: Craig, Michael R. (CDC/OID/NCEZID) <br/>bez7@cdc.gov>; Pantino, Elizabeth (CDC/OID/NCEZID) <ymt0@cdc.gov>

Subject: response to remaining EPA comments

Hi Susan

Attached are some responses to the remaining EPA comments. I am cc'ing CDC folks so that they are aware.

For some of these I need a little EPA help and for a few I am not sure how best to respond and am raising these issues now so that we can properly address on the phone tomorrow. I would like to set up a call for 12pm EST (5pm my time) if that is ok with you.

Thanks,

Jean

Jean B. Patel PhD, D(ABMM)
Science Team Lead
Antibiotic Resistance Coordination & Strategy
NCEZID/DHQP/OD
404.639.0361 | jpatel1@cdc.gov

From: Patel, Jean (CDC/DDID/NCEZID) [vzp4@cdc.gov]

**Sent**: 11/1/2018 7:28:10 PM

**To**: Jennings, Susan [Jennings.Susan@epa.gov]

CC: Craig, Michael R. (CDC/DDID/NCEZID) [bez7@cdc.gov]; Avery, Lacey (CDC/DDID/NCEZID) (CTR) [xmh2@cdc.gov]

Subject: Final Review of AMR Environmental Forum Executive Summary and Report

Attachments: AMR Env Forum Report combined 11012018.docx; 20181031envAMRBriefing v8.docx

#### Dear Susan

Previously you reviewed and provided comments on these documents. We incorporated your feedback, along with feedback from the meeting co-organizers: UK and Wellcome Trust. We are sending this to you now for a final review. Below are a few notes about changes:

# **Deliberative Process / Ex. 5**

If you would like to discuss any of these changes, I would like to arrange a call on Monday.

Thanks,

Jean

Jean B. Patel PhD, D(ABMM)
Science Team Lead
Antibiotic Resistance Coordination & Strategy
NCEZID/DHQP/OD
404.639.0361 | jpatel1@cdc.gov

From: Craig, Michael R. (CDC/OID/NCEZID) [bez7@cdc.gov]

**Sent**: 3/4/2016 2:22:56 AM

To: Maignan, Tawanda [Maignan.Tawanda@epa.gov]

CC: Jennings, Susan [Jennings.Susan@epa.gov]; Madden, Barbara [Madden.Barbara@epa.gov]; Rosenblatt, Daniel

[Rosenblatt.Dan@epa.gov]; Herndon, George [Herndon.George@epa.gov]

Subject: RE: Florida Citrus Greening S18 for Antibiotics

Thank you for your email. We will review and provide feedback.

Best, Michael

From: Maignan, Tawanda [mailto:Maignan.Tawanda@epa.gov]

Sent: Thursday, March 03, 2016 6:11 PM

To: Craig, Michael R. (CDC/OID/NCEZID) <br/>bez7@cdc.gov>

Cc: Jennings, Susan < Jennings.Susan@epa.gov>; Madden, Barbara < Madden.Barbara@epa.gov>; Rosenblatt, Daniel

<Rosenblatt.Dan@epa.gov>; Herndon, George <Herndon.George@epa.gov>

Subject: Florida Citrus Greening S18 for Antibiotics

Importance: High

Mr. Craig,

Again, thank you for taking the time to speak with use today and offer additional clarification on CDC's position with respect to the Section 18 for antibiotics and other uses. As discussed, we would like CDC's assistance/guidance with the type of monitoring we would like for Florida to conduct. For consideration, the following is a general summary that was provided by EPA's 152 Team on monitoring:

# **Deliberative Process / Ex. 5**

We look forward to your feedback and the contact information for Ms. Beth Bell at your earliest convenience.

Regards, Tawanda

Tawanda Maignan
Emergency Response Team Leader
Registration Division | Office of Pesticide Programs
Office of Chemical Safety & Pollution Prevention
U.S. Environmental Protection Agency (7505P)
1200 Pennsylvania Avenue, NW | Washington, DC 20460
Tel: (703) 308-8050 | Maignan.Tawanda@epa.gov

From: Patel, Jean (CDC/OID/NCEZID) [vzp4@cdc.gov]

**Sent**: 9/5/2018 12:51:24 PM

To: Jennings, Susan [Jennings.Susan@epa.gov]

CC: Craig, Michael R. (CDC/OID/NCEZID) [bez7@cdc.gov]; Pantino, Elizabeth (CDC/OID/NCEZID) [ymt0@cdc.gov]

**Subject**: response to remaining EPA comments

Attachments: AMR Env Forum Report combined\_083118 EPA Pesticide Comments.docx

Hi Susan

Attached are some responses to the remaining EPA comments. I am cc'ing CDC folks so that they are aware.

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Thanks,

Jean

Jean B. Patel PhD, D(ABMM)
Science Team Lead
Antibiotic Resistance Coordination & Strategy
NCEZID/DHQP/OD
404.639.0361 | jpatel1@cdc.gov

From: Patel, Jean (CDC/OID/NCEZID) [vzp4@cdc.gov]

**Sent**: 8/31/2018 8:00:51 PM

To: Jennings, Susan [Jennings.Susan@epa.gov]

**Subject**: Environment report

Attachments: AMR Env Forum Report combined\_083118.docx; AMR Env Forum Report combined\_080818 Clearance Edits\_EPA

comments.docx

# Susan

# Attached are two documents.

- 1. The report with EPA comments. For each EPA comment I provide a response. The edits appear in document 2. Some comments were hard to respond to. For example, there is mention of a memo with numbers and a recommendation to use those numbers. I need the memo. This was sent to CDC but I don't have it and need to make changes soon.
- 2. The most current version of the report with edits based upon EPA comments.

Thanks,

Jean

From: Patel, Jean (CDC/OID/NCEZID) [vzp4@cdc.gov]

**Sent**: 8/28/2018 1:49:42 PM

To: Jennings, Susan [Jennings.Susan@epa.gov]

Subject: AMR Env Forum Report

Attachments: AMR Env Forum Report combined\_082818 Clearance Edits Track Changes.docx

Susan

Sending as a FYI.

Attached is the latest draft with track changes. These changes are in response to comments from USDA, EPA, and Don Prater at FDA.

Our edits were focused on:

- Removing language that could be interpreted as creating new policy
- Maintaining scientific intent
- Making the report clear and readable

We plan to submit a final version for formatting on Friday of this week.

All the best,

Jean

From: Patel, Jean (CDC/OID/NCEZID) [vzp4@cdc.gov]

**Sent**: 8/22/2018 2:09:44 PM

To: Jennings, Susan [Jennings.Susan@epa.gov]
Subject: FW: Draft of Environmental AMR Report

Attachments: AMR Env Forum Report combined\_080818 Clearance Edits.docx

Hi Susan,

Any early feedback that we should respond to?

Thanks,

Jean

From: Patel, Jean (CDC/OID/NCEZID)
Sent: Monday, August 13, 2018 4:21 PM

To: Jennings.Susan@epa.gov; Nappier.Sharon@epa.gov; garland.jay@epa.gov

Cc: Avery, Lacey (CDC/OID/NCEZID) (CTR) <xmh2@cdc.gov>

Subject: Draft of Environmental AMR Report

Dear Sharon, Jay and Susan

I am sharing the current draft of the environmental AR report from Vancouver with you. We hope to finalize and release the report online in the first week of Sept. Could you please share this with folks at EPA who need to see this and send any concerns by this Friday (apologies for a short turn around). Please send science concerns only, we are still editing the writing.

Thanks for all of your help with this report and the meeting.

Jean

From: Liguori, Krista [liguori.krista@epa.gov]

**Sent**: 8/17/2018 3:42:36 PM

To: Patel, Jean (CDC/OID/NCEZID) [vzp4@cdc.gov]

CC: Avery, Lacey (CDC/OID/NCEZID) (CTR) [xmh2@cdc.gov]; Nappier, Sharon [Nappier.Sharon@epa.gov]; Jennings,

Susan [Jennings.Susan@epa.gov]; Garland, Jay [Garland.Jay@epa.gov]

**Subject**: RE: Draft of Environmental AMR Report

Attachments: AMR Env Forum Report combined 080818 Clearance Edits-Krista Liguori.docx

Hi Jean,

The report looks great and I look forward to seeing the published version! My comments are attached here.

Best,

Krista Liguori, MSPH
ORISE Participant
US Environmental Protection Agency
Office of Water, Office of Science and Technology

Health and Ecological Criteria Division | Human Health Risk Assessment Branch

From: Patel, Jean (CDC/OID/NCEZID) [mailto:vzp4@cdc.gov]

Sent: Tuesday, August 14, 2018 9:43 AM

To: Nappier, Sharon <Nappier.Sharon@epa.gov>; Jennings, Susan <Jennings.Susan@epa.gov>; Garland, Jay

<Garland.Jay@epa.gov>

Cc: Avery, Lacey (CDC/OID/NCEZID) (CTR) <mh2@cdc.gov>; Liguori, Krista liguori.krista@epa.gov>

Subject: RE: Draft of Environmental AMR Report

Thanks Sharon and Krista.

From: Nappier, Sharon < Nappier. Sharon@epa.gov>

**Sent:** Tuesday, August 14, 2018 8:24 AM

**To:** Patel, Jean (CDC/OID/NCEZID) < <u>vzp4@cdc.gov</u>>; Jennings, Susan < <u>Jennings.Susan@epa.gov</u>>; Garland, Jay < Garland.Jay@epa.gov>

Cc: Avery, Lacey (CDC/OID/NCEZID) (CTR) <mh2@cdc.gov>; Liguori, Krista Liguori, Krista@epa.gov>

Subject: RE: Draft of Environmental AMR Report

Hi Jean -

Thanks for sending. I'm leaving town tomorrow for a few weeks and won't have time to review this document. I've forwarded to Krista Liguori (cc:d) in our office for review.

Thanks, Sharon

From: Patel, Jean (CDC/OID/NCEZID) [mailto:vzp4@cdc.gov]

Sent: Monday, August 13, 2018 4:21 PM

To: Jennings, Susan < <a href="mailto:Jennings.Susan@epa.gov">
Jennings, Susan@epa.gov</a>; Rappier, Sharon < <a href="mailto:Nappier.Sharon@epa.gov">Nappier, Sharon@epa.gov</a>; Garland, Jay

<Garland.Jay@epa.gov>

Cc: Avery, Lacey (CDC/OID/NCEZID) (CTR) < xmh2@cdc.gov>

**Subject:** Draft of Environmental AMR Report

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Thanks for all of your help with this report and the meeting.

Jean

From: Patel, Jean (CDC/OID/NCEZID) [vzp4@cdc.gov]

**Sent**: 8/13/2018 8:20:30 PM

To: Jennings, Susan [Jennings.Susan@epa.gov]; Nappier, Sharon [Nappier.Sharon@epa.gov]; Garland, Jay

[Garland.Jay@epa.gov]

CC: Avery, Lacey (CDC/OID/NCEZID) (CTR) [xmh2@cdc.gov]

**Subject**: Draft of Environmental AMR Report

Attachments: AMR Env Forum Report combined\_080818 Clearance Edits.docx

Dear Sharon, Jay and Susan

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Thanks for all of your help with this report and the meeting.

Jean

From: Patel, Jean (CDC/OID/NCEZID) [vzp4@cdc.gov]

**Sent**: 5/18/2017 3:57:45 PM

**To**: Jennings, Susan [Jennings.Susan@epa.gov]

Subject: MOU

Attachments: CDC antibacterial resistance MOU 05-11-17.sbg.docx

This is good to go on our end. Can you please add the name of the EPA person signing? Do you want to sign first and then CDC (doesn't matter to me).

Jean

From: Patel, Jean (CDC/OID/NCEZID) [vzp4@cdc.gov]

**Sent**: 4/10/2017 2:19:11 PM

**To**: Jennings, Susan [Jennings.Susan@epa.gov]

Subject: new version

Attachments: EPA MOU V3.1.docx

Sorry about that...

From: Bloom, Raanan [Raanan.Bloom@fda.hhs.gov]

**Sent**: 4/7/2017 5:37:24 PM

To: Lazorchak, Jim [Lazorchak.Jim@epa.gov]; Jennings, Susan [Jennings.Susan@epa.gov]; Ann Marie Gebhart

[AnnMarie.Gebhart@cadmusgroup.com]; Anna Weber [Anna.Weber@cadmusgroup.com]; Barry McIntyre [mcintyrebs@mail.nih.gov]; Behl, Betsy [Behl.Betsy@epa.gov]; Clinton Williams [clinton.williams@ars.usda.gov]; Flaherty, Colleen [Flaherty.Colleen@epa.gov]; Zahner, Holly [Holly.Zahner@fda.hhs.gov]; Vesper, Hubert (CDC) [hav2@cdc.gov]; Laurenson, James [James.Laurenson@fda.hhs.gov]; John Martin [John.Martin@cadmusgroup.com]; Kathy Lee [klee@usgs.gov]; Linda Baetz [linda.l.baetz.civ@mail.mil]; Lisa Strutz [lisa.s.strutz.civ@mail.mil]; Backer, Lorraine C (CDC) [lfb9@cdc.gov]; Michael H. Fulton [mike.fulton@noaa.gov]; Rogers, Emily [rogers.emily@epa.gov];

Rogers, John M. [Rogers.John@epa.gov]; Strong, Jamie [Strong.Jamie@epa.gov]

Subject: Nature Reviews | Microbiology | Call of the wild: antibiotic resistance genes in natural environments

Attachments: nrmicro2312.pdf

Interesting read.

Nature Reviews | Microbiology | Call of the wild: antibiotic resistance genes in natural environments

# Ron

Raanan (Ron) A. Bloom, Ph.D. Senior Toxicologist/Environmental Team Center for Drug Evaluation and Research U.S. Food and Drug Administration 10903 New Hampshire Ave. Silver Spring, MD 20993-0002

Phone: 301-796-2185

e-mail: raanan.bloom@fda.hhs.gov



From: Lazorchak, Jim [mailto:Lazorchak.Jim@epa.gov]

Sent: Wednesday, February 15, 2017 11:24 AM

**To:** Jennings, Susan; Ann Marie Gebhart; Anna Weber; Barry McIntyre; Behl, Betsy; Clinton Williams; Flaherty, Colleen; Zahner, Holly; Vesper, Hubert (CDC); Laurenson, James; John Martin; Kathy Lee; Linda Baetz; Lisa Strutz; Backer,

Lorraine C (CDC); Michael H. Fulton; Bloom, Raanan; Rogers, Emily; Rogers, John M.; Strong, Jamie

Subject: FW: gPCR survey of blaKPC, blaNDM, and blaOXA-48 in aquatic environment impacted by wwtp effluent

Subject: gPCR survey of blaKPC, blaNDM, and blaOXA-48 in aguatic environment impacted by wwtp effluent

Ed Topp Ph.D.

Principal Research Scientist/Directeur de Recherche Agriculture and Agri-Food Canada/Agriculture et Agroalimentaire Canada Adjunct Professor, Department of Biology, University of Western Ontario Cell phone/portable 1-519-860-0235

Telephone/Téléphone: 1-519-953-6717

Facsimile/Télécopieur: 519-457-3997 1391 Sandford Str., London, ON N5V 4T3 Canada Email/Courriel ed.topp@agr.gc.ca

# REVIEWS

# Call of the wild: antibiotic resistance genes in natural environments

Heather K. Allen\*<sup>†</sup>, Justin Donato\*, Helena Huimi Wang<sup>§</sup>, Karen A. Cloud-Hansen\*, Julian Davies<sup>§</sup> and Jo Handelsman<sup>||</sup>

Abstract | Antibiotic-resistant pathogens are profoundly important to human health, but the environmental reservoirs of resistance determinants are poorly understood. The origins of antibiotic resistance in the environment is relevant to human health because of the increasing importance of zoonotic diseases as well as the need for predicting emerging resistant pathogens. This Review explores the presence and spread of antibiotic resistance in non-agricultural, non-clinical environments and demonstrates the need for more intensive investigation on this subject.

Antibiotic resistance genes in human pathogens such as methicillin-resistant <u>Staphylococcus aureus</u><sup>1</sup> have become notorious because they confound the tools that are used to treat disease [FIG. 1]. In particular, resistance determinants in pathogens are commonly encountered after the introduction of an antibiotic to clinical use, and treating human pathogens with antibiotics directly affects the frequency of resistance to those antibiotics in these pathogens<sup>1-4</sup>.

The presence of antibiotic resistance elements in pathogenic bacteria is made all the more problematic because of the prevalence of horizontal gene transfer, the process by which bacteria acquire genes from the environment<sup>5</sup>. Many of the known antibiotic resistance genes are found on transposons, integrons or plasmids, which can be mobilized and transferred to other bacteria of the same or different species. There is evidence of the transfer of resistance elements to known human commensal bacteria and pathogens<sup>6,7</sup>, and gene transfer in the human intestinal microbiome is extensive<sup>8</sup>.

What are the sources and reservoirs of these transferable genes? A full understanding of the pressures and circumstances that lead to the evolution and dissemination of antibiotic resistance genes in pathogens is impossible without a detailed examination of the origin and role of resistance genes in natural environments. This Review discusses the environmental sources of antibiotic resistance, the functions and roles of resistance genes in microbial ecology and the ways by which those genes may be disseminated in response to human antibiotic use.

# Selection pressures in the environment

Antibiotics are essential for the treatment of bacterial infections in humans and animals; it is therefore a top priority to preserve their efficacy. For decades, clinicians and scientists have called for the prudent use of antibiotics, in an effort to slow the development and epidemic spread of resistance9-11. Prudent use of antibiotics in humans demands that physicians establish that a bacterial infection is responsible for the patient's symptoms before an antibiotic prescription is written. By contrast, in agriculture antibiotics are used in the absence of acute infection. Some of the same antibiotics that are used to treat human pathogens, such as amoxicillin and erythromycin, are also used to treat disease, promote growth and improve feed efficiency in animals  $^{12}$  (  $\mbox{BOX\ 1}\mbox{)}.$  Just as in hospital settings, the agricultural use of antibiotics selects for antibiotic resistance, arguably in a more widely disseminated fashion owing to the farm-wide administration of prophylactic antibiotics in feed and water. Antibiotics from both urban and agricultural sources persist in soil and aquatic environments, and the selective pressure imposed by these compounds may affect the treatment of human diseases13,14. As another example, the prophylactic use of antibiotics in fish farms has led to a rise in the number of resistant bacteria<sup>15</sup>. Strikingly, these resistant bacteria can transfer the resistance genes to human pathogens 16. The selection pressure applied by the antibiotics that are used in clinical and agricultural settings has promoted the evolution and spread of genes that confer resistance, regardless of their origins (FIG. 2).

New Haven, Connecticut 06520, USA. Correspondence to J.H. e-mail: jo.handelsman@yale.edu

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Biology, Vale University,

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Training Program, University of Wisconsin–Madison, 1550 Linden Dr., Madison, Wisconsin 53706, USA.

Department of Microbiology and Immunology, University of British Columbia, 2350 Health Sciences Mall, Vancouver, British Columbia V671Z3, Canada.

Department of Molecular, Cellular, and Developmental

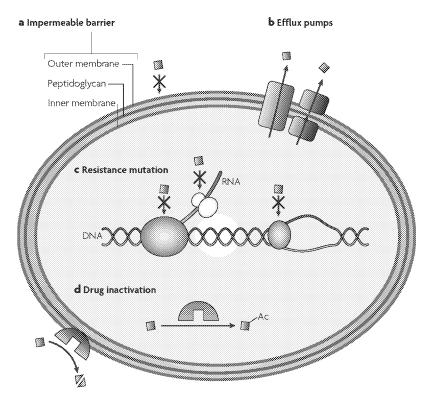


Figure 1 | Mechanisms of antibiotic resistance in a Gram-negative bacterium. a | Impermeable barriers. Some bacteria are intrinsically resistant to certain antibiotics (blue squares) simply because they have an impermeable membrane or lack the target of the antibiotic. b | Multidrug resistance efflux pumps. These pumps secrete antibiotics from the cell. Some transporters, such as those of the resistance-nodulation-cell division family (pink), can pump antibiotics directly outside the cell, whereas others, such as those of the major facilitator superfamily (red), secrete them into the periplasm. c | Resistance mutations. These mutations modify the target protein, for example by disabling the antibiotic-binding site but leaving the cellular functionality of the protein intact. Specific examples include mutations in the gyrase (green), which cause resistance to floroquinolones, in RNA polymerase subunit B (orange), which cause resistance to rifampicin, and in the 30S ribosomal subunit protein S12 (encoded by rpsL) (yellow), which cause resistance to streptomycin. d | Inactivation of the antibiotic. Inactivation can occur by covalent modification of the antibiotic, such as that catalysed by acetyltransferases (purple) acting on aminoglycoside antibiotics, or by degradation of the antibiotic, such as that catalysed by  $\beta$ -lactamases (brown) acting on  $\beta$ -lactam antibiotics. Ac, acetyl group.

The use (and misuse) of antibiotics by humans is probably not the only selective pressure for antibiotic resistance in natural microbial communities: compounds and conditions that occur in these communities may provide additional selection pressures. Indeed, most antibiotics are produced by strains of fungi and bacteria that occur naturally in all environments, including soil17 (FIG. 2). Most antibiotic-producing strains carry genes encoding resistance to the antibiotics that they produce18,19, and these genes are usually found in the same gene cluster as the antibiotic biosynthesis pathway genes<sup>17,20</sup>. Antibiotics produced in the environment may exert selective pressure on neighbouring organisms. However, it is difficult to determine the natural concentrations of antibiotics in soil microcosms or the extent of the selective pressure that they may pose.

Accidental resistance genes. The presence of various potentially offensive compounds and conditions in nature might select for specific or nonspecific mechanisms of antibiotic resistance (FIGS 1,2). Bacteria cultured from the marine air-water interface were shown to be more highly resistant to antibiotics than bacteria cultured from the bulk water21, and numerous conditions, including radiation and pollution, that may select for antibiotic resistance in this habitat have been suggested, although the mechanisms of cross resistance to antibiotics are unknown. Some genes confer antibiotic resistance but are likely to have other primary roles in the environment<sup>22</sup>. Certain classes of efflux pumps, for example, offer general mechanisms of resistance, because they pump various toxins, such as heavy metals and other toxic molecules, out of cells23,24. For some chromosomally encoded multidrug resistance pumps, such as those of the resistance-nodulation-division family, antibiotic resistance is now thought to be an associated function of the primary role that they serve in the environment 24, which might be, for example, to provide tolerance to toxic compounds. The microbial communities of insect guts that had no known exposure to antibiotics contain efflux pumps that confer resistance to antibiotics when transferred to Escherichia coli<sup>25,26</sup>. Both oil fly larvae and gypsy moth larvae ingest compounds that might stress microorganisms; oil fly larvae eat organic solvents, and gypsy moth larvae feed on diverse plants that produce various toxic compounds. In Shewanella oneidensis, a bacterium that lives in sediment, the multidrug efflux transporter gene mexF enhances fitness in the environment and confers resistance to chloramphenicol and tetracycline in the laboratory<sup>27</sup>. Further information on the roles of efflux pumps in bacteria can be found in REF. 28.

# The movement of antibiotic resistance genes

Physical forces. Physical forces, such as those created by wind and watershed, are important drivers of the spread of antibiotic resistance genes (FIG. 2). Antibiotics and their resistance genes have been widely distributed in the environment since before the introduction of antibiotic chemotherapies, but human activities have probably increased the prevalence of resistant bacteria in the air and water. As a result, antibiotic resistance is more common in E. coli and S. aureus isolates from air inside the home than in isolates from outside29,30, although a study of sulphonamide resistance in E. coli detected more antibiotic-resistant isolates in dust outside homes than in dust inside homes in Mexico31. Marine and freshwater ecosystems also contain bacteria from many sources, including antibiotic-resistant bacteria from anthropogenic sources<sup>32</sup>. Even bacteria from environments that are thought to be stationary, such as soil, can be moved by the forces of nature; one example is the intercontinental transport of bacteria on desert dust<sup>33</sup>.

Animals. Wild animals provide a biological mechanism for the spread of antibiotic resistance genes (FIG. 2). Proximity to human activities influences the antibiotic resistance profiles of the gut bacteria of wild

# FOCUS ON ANTIMICROBIAL RESISTANCE

# Resistotype

The antibiotic resistance genotype and phenotype of a bacterium.

mammals, which live in densely populated microbial habitats in which antibiotics select for resistance. Ninety percent of the bacterial isolates from mice and voles captured in rural England were resistant to  $\beta$ -lactam antibiotics<sup>34</sup>. By contrast, the faecal enterobacteria of wild elk, deer and voles in Finland have almost no resistance<sup>35</sup>. For the most part, Finland is less densely populated than England; therefore, these findings might suggest that human activities influence antibiotic resistance in bacterial communities in wild animals, although other influences that affect the frequency of antibiotic resistance cannot be eliminated (including differences in the testing methodologies used or variation in the intrinsic antibiotic resistance of the isolate populations). Likewise, a study of E. coli isolates from wild animals in Mexico and in Australia found a higher frequency of antibiotic resistance in the isolates from Mexico<sup>36</sup>. It was suggested that this difference may be due to widespread human settlement and use of antibiotics in Mexico along with possible selection pressures from the host animals36. Other studies demonstrate a similar association — African baboons and apes that are in contact with humans harbour more antibiotic-resistant enteric bacteria than those that dwell in areas that are remote from human activity 37,38.

Wild birds carry a reservoir of antibiotic-resistant bacteria with the potential for long-distance dissemination. Birds, and migratory waterfowl in particular, can travel great distances and inhabit a wide variety of environments, from agricultural lagoons to remote mountain lakes, and can potentially spread resistance genes along the way. Proximity to human activity increases the number of the antibiotic-resistant bacteria that are

associated with wild birds. Gulls and geese nesting near waste or agricultural water harbour more antibioticresistant E. coli than do birds associated with unpolluted water 39,40. Antibiotics also seem to affect resistance in remote bird populations: in arctic birds, 8% of E. coli isolates were recently found to be resistant to at least 1 of 17 antibiotics tested, and 4 were resistant to 4 or more antibiotics41. One isolate was resistant to cefadroxil, cefuroxime and cefpodoxime, a pattern that is common in clinical isolates41. Many birds breed in the arctic and migrate to up to six continents. They probably acquire antibiotic-resistant bacteria either from environments that are under human influence or from other birds that contact those environments, illustrating the great geographical distances that can be travelled by resistance genes that are associated with human selective pressures.

One study looking at the effect of the proximity of human activity on the presence of antibiotic resistance genes found no antibiotic-resistant E. coli from remote animal populations but notable populations of antibiotic-resistant E. coli in animals that were proximal to anthropogenic activity42. Animals that live with humans, including pets such as cats and dogs, are reservoirs of antibiotic-resistant bacteria as a result of both antibiotic treatment for disease and the transfer of resistant bacteria from humans43. The data suggest that exposure to antibiotics has affected antibiotic resistance in the enteric bacteria of wild animals, although many more studies using standardized methods are required to define this impact. More complete profiles of antibiotic resistance in wild animals will contribute to our understanding of the origins and roles of antibiotic resistance genes in natural intestinal microbial communities, which, in turn, will help us manage emerging zoonotic diseases.

# Box 1 | Antibiotics in food production

Antibiotics are used in diverse settings for food production. Animals are treated with antibiotics for both curing disease and promoting growth<sup>7</sup>, fruit trees are often treated prophylactically with antibiotics to control bacterial infections <sup>98</sup>, and aquaculture relies on antibiotics to manage infectious disease <sup>15</sup>. In each of these situations, the effects of the antibiotics extend beyond the site of use. Antibiotics applied in animal farming operations leach into waterways and groundwater; in many aquaculture settings, antibiotics diffuse into the water surrounding the pens; and antibiotics sprayed on plants can drift aerially.

The Food and Agriculture Organization (FAQ) of the United Nations has the task of monitoring and compiling global statistics about the international regulation of pesticide use. The philosophy and legality of the administration of antibiotics in agricultural settings vary among countries. In 1985, Sweden enacted the Feeding Stuffs Act, which outlawed the administration of antibiotics to livestock for growth promotion  $^{99}$ , in stark contrast to the many industrial countries that use vast quantities of antibiotics for this purpose. Even countries that have adopted similar overall patterns of regulation vary in the specifics. For example, the United Kingdom, the United States, Norway, Mexico, India and Indonesia have approved the use of oxytetracycline in aquaculture, whereas among these same countries only Mexico and Indonesia permit the use of enrofloxacin  $^{100}$ .

Some governments have taken action in response to public concern about the use of antibiotics in agriculture. Consumers are also directly shaping farm practices, leading McDonald's to purchase only antibiotic-free beef for its globally sourced restaurants<sup>101</sup>. As more large corporations and governments follow suit, antibiotic application practices in agriculture might be reduced and standardized globally.

Humans. Antibiotic-resistant bacteria have been found in even the most secluded communities, although proximity to dense human populations affects the antibiotic resistotypes that are found. For example, although antibiotic-resistant Salmonella and Shigella species were isolated from humans living far from Kathmandu, Nepal, there were far fewer than were isolated from humans living near to the city44. High levels of antibiotic resistance were also found in E. coli from an isolated human population in Bolivia45, and the resistance genes in the remote community (such as β-lactamase TEM (blaTEM)like genes and the aminoglycosyl adenyltransferase gene aadA1) closely matched genes from antibioticexposed environments<sup>46</sup>. As this population has little access to modern health care, and contact with people outside the community is minimal, the results show that antibiotic resistance in this remote community is entirely due to a diverse array of resistance genes that had immigrated from elsewhere. Despite the barriers, antibiotic resistance genes have been transmitted to the most isolated human populations, where they exist even in the absence of an obvious selection pressure.

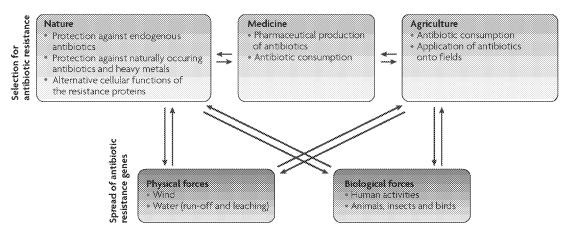


Figure 2 | Sources and movement of antibiotic resistance genes in the environment. Resistance genes exist naturally in the environment owing to a range of selective pressures in nature. Humans have applied additional selective pressure for antibiotic resistance genes because of the large quantities of antibiotics that we produce, consume and apply in medicine and agriculture. Physical and biological forces also cause widespread dissemination of resistance genes throughout many environments.

### Antibiotic resistance in natural communities

Little is known about the selection pressures on antibiotic resistance genes in the era before antibiotics were turned into pharmaceuticals or in remote environments with little direct human contact. A more comprehensive understanding of the natural roles of putative antibiotic resistance genes will provide important information on their origins and functions.

The pre-antibiotic era. The only environments that are truly exempt from the influence of human antibiotic use existed before the antibiotic era. The time before the introduction of sulphonamides, which occurred in the late 1930s, can be considered 'antibiotic naive', in the sense that no industrial production of antibiotics took place. However, heavy metals were used for disease treatment for centuries prior to the use of antibiotics, and this may have selected for genes encoding both heavymetal and antibiotic resistance<sup>47</sup>. Retrospective studies show that resistance genes were present in bacteria that did not produce antibiotics before the widespread dissemination of the drugs. Out of 30 E. coli strains that were lyophilized before 1950, 4 were resistant (to various degrees) to the 8 tested antibiotics, and each resistance element could conjugate into E. coli48. In another analysis of 433 enterobacterial strains collected from around the world between 1917 and 1952 (known as the Murray collection), 24% could transfer plasmids and 11 strains were resistant to ampicillin or tetracycline, although the resistance was not conjugative49. More recent analysis of antibiotic resistance profiles from enteric bacteria collected before and after the introduction of antibiotics mirrors these findings<sup>50</sup>. Thus, determinants of antibiotic resistance existed naturally and were probably subject to horizontal transfer long before the extreme selection pressure that was imposed in the antibiotic era. This predisposition for the genetic exchange of resistance elements is certain to have facilitated the rapid outgrowth of antibiotic resistance in pathogenic bacteria.

Soil. Owing to the movement of antibiotics and resistance genes on the wind and on feathers, it is unlikely that any environment can be considered truly pristine. However, despite the movement of soil particles by physical forces, soil itself is a stationary complex, and some soils are far removed from human influences. Thus, studies of antibiotic resistance in soil show that environmental bacteria harbour antibiotic resistance genes independently of human activities.

Culturable bacteria in soil harbour genes encoding enzymes that degrade or otherwise inactivate antibiotics. Bacteria that grow on antibiotics as the sole carbon and nitrogen sources include: Pseudomonas fluorescens grown on streptomycin51; P. fluorescens52, Burkholderia cepacia53 and eight unidentified strains54 grown on penicillin; an unidentified Streptomyces sp. isolate and Streptomyces venezuelae grown on chloramphenicol<sup>55,56</sup>; a Flavobacterium sp. isolate grown on chloramphenicol<sup>57</sup>; and various bacteria, mostly of the phylum Proteobacteria, grown on various antibiotics<sup>58</sup>. In addition to antibiotic degradation, culturable soil bacteria use many mechanisms of resistance to antibiotics. In the most comprehensive study to date on antibiotic resistance in one soil species, over 400 actinomycetes cultured from forest, agricultural and urban soils were found to have highly varied resistance profiles; moreover, some exhibited resistotypes that had not been seen before, such as inactivation of telithromycin by a novel structural modification59.

# The roles of antibiotics and resistance in nature

The discovery of the great therapeutic potential of microbial compounds in both the laboratory and the clinic led to the preconception that antibiotic activity must be important and widespread in nature. This led to an almost complete disregard of the other potential functions of natural products from microorganisms. On the basis of limited genomic studies, it is thought that microbial populations are capable of

Pristine
Unspoiled or unpolluted by human activities.

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producing a wide range of bioactive small molecules (the parvome<sup>60</sup>), only a handful of which have been isolated, identified and used as antibiotics and other types of therapeutics. Bacteria of the phylum Actinobacteria<sup>61</sup>, a huge taxonomic group that is characterized by a high genomic GC content and that comprises diverse genera, all produce complex bioactive small molecules. It can be estimated that actinobacteria make millions of such molecules. Most of these molecules cannot be detected under laboratory conditions, and the few that have been identified include the most important antibiotics. It has been suggested that antibiotics have been produced for over 500 million years, dating back to the Cambrian period and the emergence of vertebrate fish62. Antibiotic-like molecules, or at least their component parts, are likely to be even older than this — the non-protein amino acids that are found as components of peptide antibiotics have been detected in meteorites and other primordial sources<sup>63</sup>.

The roles of antibiotics in microbial communities. Using war as a metaphor for the interaction of microorganisms, the activities of antibiotics in the laboratory and in clinical applications led to the assumption that these molecules have hostile roles in nature. The number of such bioactive molecules in any given environment must provide a considerable armamentarium. However, the in situ concentrations of the compounds with antibiotic activity have never been measured, and there are few ecological examples of probable antibiotic functions for microbial products in nature. One example is the fungus-growing ant system, in which ants carry an antibiotic-producing actinomycete (a Pseudonocardia sp.) on their cuticle and use this bacterium specifically for biocontrol of the fungal garden parasite, Escovopsis sp. 64,65. A second example is in the biocontrol of the causative agent of potato scab, Streptomyces scabies str. RB4, by the antibiotic-producing suppressive strain, Streptomyces diastatochromogenes str. PonSSII66. Many factors may contribute to disease suppression, but the fact that antibiotic-resistant strains of the pathogen are restored in their ability to cause disease is evidence for a direct role for antibiosis66. Because of the sparse evidence for widespread antibiotic-mediated killing in nature, it is important to investigate the role of sublethal doses of antibiotics in microbial communities.

The demonstration of quorum-sensing reactions in a range of microbial species opened up a profitable field of investigation that has had implications for research into various aspects of bacterial lifestyles, such as pathogenesis, community structure and biofilm formation<sup>67</sup>. These all involve the production of specific bioactive compounds that, at low concentrations, activate biochemical pathways in one or more target organisms. Interestingly, some autoinducers used in quorum sensing have antibiotic activity at higher concentrations and may also provoke changes in eukaryotic host organisms or tissues<sup>68</sup>. These studies have led to the realization that bioactive small molecules (other than amino acids, sugars and nucleic-acid

bases) have important roles in microbial biology<sup>69</sup>. For example, quinolones, phenazines and pheromones are bioactive small molecules that exist widely in nature, and they each possess a range of biological functions.

In recent years, several antibiotics and other bioactive molecules (such as bacteriocins) have been tested for activity at concentrations below those needed for the inhibition of cell growth. Almost all of the tested compounds exhibit hormesis 70,71. This suggests that the compounds constitute a new form of signalling network, in which the receptors for the small molecules are cytoplasmic macromolecular structures such as ribosomes and the DNA replication, RNA replication and cell wall synthesis complexes72. Note that many of these receptors were previously identified as the inhibitory targets for the bioactive molecules. The binding of the ligands to their receptors at low concentrations initiates a profusion of different transcription patterns, depending on the nature of the ligand and the target. Modulation of host transcription leads to metabolic and behavioural changes in the microorganisms, as has been described in several reports<sup>70,73</sup>. These changes can be assumed to be signalling responses that adjust metabolism in mixed microbial communities.

The role of antibiotic resistance genes in microbial communities. As mentioned above, the production of an antibiotic is associated with the presence of genes encoding one or more self-protection processes; antibiotic biosynthesis gene clusters always encode one or more potential resistance proteins that are either specific to the compound being made (for example, they modify the compound or target) or multifunctional (for example, efflux systems). In addition to the socalled self-resistance function, the resistance genes that are contiguous with the biosynthesis genes could be involved in regulation of the biosynthesis pathway. One study that supports this concept found genes encoding export proteins embedded in the actinorhodin biosynthesis pathway of Streptomyces coelicolor 19, but is this yet another example of anthropocentric reasoning? Evidence shows that antibiotic resistance genes are common in natural environments and existed, even on plasmids, before the use of antibiotics. Phylogenetic analyses date the origin of serine β-lactamases at over 2 billion years ago and suggest that many of these enzymes have been plasmid encoded for millions of years74.

Another form of resistance in isolates that do not produce antibiotics is mutation of the target gene product, which reduces or prevents inhibition by antibiotic binding. However, antibiotic resistance may not be the only consequence of these mutations, as they are often pleiotropic. These types of mutations have been found frequently in environmental bacteria, which are therefore, presumably, unresponsive to a specific small molecule signal in the environment. When soil bacteria were screened for isolates that were resistant to known antimicrobials such as the fluoroquinolones, it was found that the isolates had independent alleles of the DNA gyrase subunit A gene (gyrA) with different

# Parvome

The range of biologically active, low-molecular-mass (< 5 kDa) compounds that are produced by defined biosynthetic pathways in bacteria, yeast, plants and other organisms.

### Antibiosis

An interaction between microorganisms involving a small molecule that is produced by one organism and detrimental to the other.

# Hormesis

A dose-dependent response phenomenon shown by bloactive compounds and drugs, such that they have contrasting activities at low (subinhibitory) and high (inhibitory) concentrations.

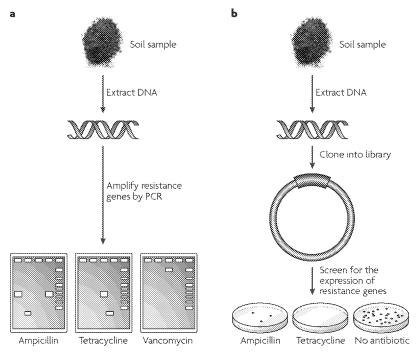


Figure 3 | **Detecting antibiotic genes in natural samples.** a | A PCR-based approach. DNA is extracted from bacteria in a soil sample and resistance genes are amplified with resistance gene-specific primers and detected by gel electrophoresis. b | Functional metagenomics. DNA is extracted from soil samples and cloned into libraries. These libraries are introduced into *Escherichia coli* or another amenable host, and the transformants are tested for drug resistance.

levels of resistance75. Subsequent studies have shown that spontaneous mutations causing resistance often lead to a range of metabolic phenotypes, including variations in the ability to use different carbon, nitrogen or phosphate sources for growth76. In addition, mutations in ribosomal proteins that conferred resistance to streptomycin, spectinomycin or macrolides were found to cause a range of altered phenotypes, as shown by phenotypic array studies (H. H. Wang and J. Davies, unpublished observations). Bacteria carrying these mutations were selected under laboratory conditions in the presence of an antibiotic, but in the environment the selection could alternatively be the ability to grow on an available peptide or the presence of a particular carbon or phosphorus source. Thus, the widespread presence of antibiotic-resistant strains in the environment may have arisen in response to various selective pressures. It is clear that more extensive studies of the roles of natural resistant strains and their diverse phenotypes are needed.

In addition to the alternative cellular and environmental roles of known antibiotic resistance genes, other types of genes that contribute to resistance have been recognized. Studies undertaken at the species level revealed an extensive set of genes that contribute to the antibiotic resistance phenotype but that primarily encode proteins with other functions in the cell (the so-called intrinsic resistome). In *E. coli*, for example, 4,000 random single-gene knockouts were screened for hypersensitivity to antibiotics<sup>77,78</sup>. Of these, 140

knockouts were identified that increased the sensitivity to at least 1 of 7 antibiotics77. Some genes were implicated in resistance to many types of antibiotics (for example, an insertion in the gene encoding the DNA helicase exonuclease V subunit-y (recC) increases susceptibility to ciprofloxacin, rifampin, sulphamethoxazole and metronizadole) and others were involved in resistance to a specific antibiotic (for example, an insertion in the transcriptional regulatory gene phoP increases susceptibility to ampicillin)77. Similar studies were performed in Pseudomonas aeruginosa79,80 and Acinetobacter baylyi 81, revealing that there is little overlap between the intrinsic resistomes of different organisms. These results implicate possible targets for antibiotic potentiators and illustrate the breadth of the genes, even in a single organism, that can contribute to the overall environmental antibiotic resistome.

# Challenges in studying natural resistance

Detecting antibiotic resistance genes. The application of culture-independent approaches, such as PCR and metagenomics, to the study of antibiotic resistance in the environment has uncovered the vast diversity of antibiotic resistance genes in soil bacteria (FIG. 3). A prairie soil was analysed by PCR for the presence of genes encoding TEM-type β-lactamases. Numerous polymorphisms of the TEM sequence were discovered in this prairie soil as well as in soil containing transgenic plants<sup>82</sup>. However, certain Tag polymerases have been shown to be contaminated with DNA that encodes TEMtype β-lactamases83 (B. Converse and J. Handelsman., unpublished observations), indicating that precautions need to be taken when using PCR methods to detect TEM-related β-lactamases. PCR has also been used to detect vancomycin<sup>84</sup> and gentamicin<sup>85</sup> resistance genes in unamended soils, revealing sequences that are closely related to known genes. Primers for tetM, one of the known tetracycline resistance genes, were used to analyse unamended garden soils by PCR but detected no related tetracycline resistance genes<sup>86</sup>. PCR is therefore a powerful tool to detect potential antibiotic resistance genes in soil environments.

In contrast to PCR, functional metagenomics can be used to query an environment for genes that are not closely related to known resistance genes. Functional metagenomics is the study of the collective genome of a group of organisms by cloning DNA directly from an environmental sample into a host organism (often E. coli) followed by screening or selecting for the desired function87. When applied to a Wisconsin remnant oak savannah soil site, functional metagenomics yielded diverse and new antibiotic resistance genes, including nine aminoglycoside resistance genes and one tetracycline resistance gene<sup>88</sup>. Six of the aminoglycoside resistance genes encoded 6'-N-acetyltransferases, and a phylogenetic analysis of these enzymes at the amino acid level showed that they cluster together and are divergent from previously known 6'-N-acetyltransferases. The same method was applied to the metagenome of an Alaskan soil that was distant from anthropogenic activities, in

A compound or molecule that augments the activity of an antibiotic.

# Box 2 | Human exposure to antibiotic-resistant bacteria in wildlife

Potential routes for human contact with wild animals and their microbiota, which may contain antibiotic-resistant strains, include:

- Translocation of wildlife into suburban areas owing to game release, habitat destruction, pollution and changes to water storage, irrigation or the climate.
- \*Ecotourism, hunting and camping
- \*Exotic foods, wet markets, bushmeat and game farms.
- \*Exotic pets and the long-distance transport of live animals.
- \* Zoos, aquaria, wildlife safari parks and circuses.
- \* Trapping or rearing of fur-bearing animals.

search of resistance to  $\beta$ -lactam antibiotics. This study revealed 13  $\beta$ -lactamases (including 1 bifunctional enzyme) that represent each of the 4 known classes of  $\beta$ -lactamases but that are deeply divergent from and ancestrally related to the  $\beta$ -lactamases found in clinical isolates. Interestingly, none of the functional  $\beta$ -lactamases from the Alaskan soil metagenome were related to TEM-type  $\beta$ -lactamases, which is in contrast to the results of the PCR-based investigation of prairie soil. Functionally characterizing the metagenomes of bacterial communities from a variety of environments will expand our knowledge of the potential sources and novel alleles of antibiotic resistance genes.

Part of the challenge of addressing and reviewing the big questions surrounding the ecology of antibiotic resistance genes in the environment is that inconsistent methods have been used to monitor the resistance properties of environmental bacteria. Most studies of resistance in bacteria from the environment are based on culturing followed by selection. However, the method of resistance determination is not standardized: therefore, the data on antibiotic resistance in the environment come from studies that have used a range of media types, antibiotic concentrations and incubation periods. This makes it difficult to compare results between environments. For example, Antarctic marine waters contain copious antibiotic-resistant bacteria, including many isolates that are resistant to ampicillin<sup>90</sup>. However, resistance was determined by growth on 50 μg ml<sup>-1</sup> ampicillin, which is not consistent with other studies of antibiotic resistance in aquatic environments or with how resistance is defined for clinical isolates, which are tested for minimum inhibitory concentration according to standard protocols91. The absence of guidelines for resistance studies of environmental bacteria makes it difficult to draw conclusions about a single environment or to make comparisons between environments.

The inconsistencies in the methodologies are further aggravated by the infrequent and incomplete monitoring of antibiotic resistance in natural environments. The intestinal microbiota of wild animals, for example, have rarely been examined for carriage of antibiotic resistance genes. Little is known about these bacteria more generally 92, despite the alarming statistic that in the past 2 decades approximately 75% of all types of emerging human diseases came from wildlife<sup>93</sup>. As

potential routes for human contact with wild animals expand (for example, through translocation of wildlife into suburban areas owing to habitat destruction and an increase in the exotic food and pet trades), the potential for bacterial transfer also increases (BOX 2). The data on antibiotic resistance in wild animals also show the need for multiple strategies to be used to fill our knowledge gaps. For example, less than 1% of the bacteria in the environment are culturable by standard techniques, although for some environments this estimate is conservative. Despite the known limitations of culturing, nearly all studies of antibiotic resistance in wild animals are based on culturing for enteric bacteria. However, considering that the spread of antibiotic resistance genes by horizontal gene transfer occurs between diverse bacteria with ease and that resistance genes are maintained even in the absence of selection 8,94, it is important to characterize the resistance genes in the entire community, including both culturable and unculturable strains. In addition, culture-independent techniques have the potential to carry microbial ecologists beyond gene definition and into gene expression studies. Techniques such as reverse transcription PCR, when coupled with metagenomics, enrich studies by investigating which genes are expressed across the entire community. Both culturedependent and culture-independent approaches have their limitations, so combining these approaches will develop the most comprehensive portrait of the resistance profile of a microbial community, which will form the basis for understanding the effects of environmental resistance genes on human pathogens and the role of antibiotic resistance genes in unperturbed communities.

### Conclusions

Little is known about the antibiotic resistomes<sup>59</sup> of the vast majority of environmental bacteria, although there have been calls for a greater understanding of the environmental reservoirs of antibiotic resistance and their potential impacts on clinically important bacteria<sup>95,96</sup>. The data on antibiotic resistance before the antibiotic era and in soil highlight how little we know about the ecology of antibiotic resistance genes in the wild. We do not have a complete picture for any environment of all of the types of resistance genes in both the cultured and uncultured community. Soil is particularly challenging to assess, because of its chemical and physical heterogeneity (soil displays variation on a scale of 1 metre or less)97. Despite the gaps in our knowledge, it is clear that some organisms and some environments harbour antibiotic resistance genes irrespective of the human use of antibiotics. The prevalence and diversity of resistance genes in the environment inspire hypotheses about the native roles of so-called resistance genes in natural microbial communities. Considering that antibiotic treatment is our primary, and in many cases only, method of treating infectious diseases, we conclude that more detailed studies of environmental reservoirs of resistance are crucial to our future ability to fight infection.

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### Acknowledgments

J. Handelsman was supported by the US Department of Agriculture Microbial Observatories Program and J. Donato was supported by the US National Institutes of Health (grant GM876102).

### Competing interests statement

The authors declare no competing financial interests.

# DATABASES

Entrez Gene: http://www.ncbi.nlm.nih.gov/gene maxF|phnF|recC

Entrez Genome Project: http://www.ncbi.nim.nih.gov/ genomepri

Burkinolderia cepacia | Escherichia coli | Pseudamonas aeruglinosa | Pseudamanas fluorescens | Shewaneila aneidenos | Staphylosocus aureus | Streptamyces coelicalor

### **FURTHER INFORMATION**

Jo Handelsman's homepage: http://bbsyele.edu/people/ jo\_bandelsman.profile

FAO: http://www.feo.org

ALL LINKS ARE ACTIVE IN THE ONLINE PDF

From: Thaker, Kaytna (CDC/OID/NCEZID) (CTR) [xxb4@cdc.gov]

**Sent**: 3/29/2018 7:48:59 PM

Subject: RE: International Environmental AMR Forum, April 4-5, 2018

Attachments: AMR ENV Forum Report 03282018.pdf; Agenda April Env. AMR meeting\_FINAL.pdf; International Environmental

AMR Forum attendee info sheet.pdf

Dear Colleague,

A copy of the draft report is attached. The draft report is still a work in progress and it will be updated and revised based on discussion during the meeting next week. Hard copies will be available at the meeting.

Also attached is a copy of the meeting agenda as well as a document containing some additional logistics information.

Please let us know if you have any questions.

Best,

Kaytna Thaker

...

Kaytna Thaker, MPH

Health Research Analyst | Northrop Grumman Corporation Antimicrobial Resistance Coordination & Strategy CDC/NCEZID/DHQP

Phone: 770-488-3709 | Email: kthaker@cdc.gov

From: Thaker, Kaytna (CDC/OID/NCEZID) (CTR) Sent: Tuesday, March 27, 2018 3:32 PM

Subject: International Environmental AMR Forum, April 4-5, 2018

Dear Colleagues,

We look forward to seeing you in Vancouver for the International Environmental AMR Forum on April 4-5.

Attached is a copy of the meeting agenda as well as a document containing some additional logistics information. A copy of the draft report will be emailed out before the end of this week.

Please let us know if you have any questions.

Best,

Kaytna Thaker

...

Kaytna Thaker, MPH

Health Research Analyst | Northrop Grumman Corporation
Antimicrobial Resistance Coordination & Strategy
Division of Healthcare Quality and Promotion (DHQP)
National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)
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# Agenda | International Environmental Antimicrobial Resistance (AMR) Forum

4-5 April 2018, Vancouver, Canada Vancouver Convention Centre, 999 Canada Place, Vancouver, B.C. V6C 0C3

East Meeting Rooms 8 and 15

Meeting Co-Chairs: CarriAyne Jones (UK Science and Innovation Network), Jean Patel (Centers for Disease Control and Prevention) and Tim Jinks (Wellcome Trust)

# **Meeting Objectives:**

The objectives of this conference are to:

- 1) Define current scientific understanding of environmental AMR;
- 2) Identify where scientific knowledge gaps exist around the presence and impact of antimicrobial resistant pathogens and antimicrobial agents in the environment; and
- 3) Explore actions that can be taken forward now, for example as part of mitigation strategies in antimicrobial resistance national action plans (NAPs), and where information gaps still present barriers for future actions.

The intended output of the meeting is a document that can be used by WHO, FAO, UNEP, research funding bodies, governments, and industry to identify actions that will address AMR in the environment, stimulate research activity, and motivate funding calls to address defined science gaps.

| Wednesday, April 4 |   |  |
|--------------------|---|--|
| 7:30-8:00am        | Light breakfast and coffee/tea              |  |
|                    | Location: East Meeting Rooms 11 and 12      |  |
| 8:00-8:10am        | Welcome and opening remarks                 |  |
|                    | Location: East Meeting rooms 8 and 15       |  |
|                    | Tim Jinks                                   |  |
|                    | Head of Drug-Resistant Infections Programme |  |
|                    | Wellcome Trust                              |  |
| 8:10-8:15am        | Introduction to the Forum                   |  |
|                    | CarriAyne Jones                             |  |
|                    | Head of Science and Innovation              |  |
|                    | British Consulate-General, Atlanta          |  |
|                    | British Consulate-General, Atlanta          |  |

| 8:15-8:25am   | Perspectives on the Public Health Importance of AMR                              |
|---------------|--|
|               | Michael Craig  |
|               | Senior Adviser, Antimicrobial Resistance Coordination and Strategy Unit          |
|               | Centers for Disease Control and Prevention                                       |
| 8:25-8:35am   | AMR in the Environment – Why should we care?                                     |
|               | Ed Topp  |
|               | Principal Research Scientist, Environmental microbiology and chemistry           |
|               | Agriculture and Agri-Food Canada   |
| 8:35-10:15am  | Session 1 - Contamination of the environment from hospital waste                 |
|               | Moderator: Kristy Buckley, Meridian Institute                                    |
|               | Presentation – Hospital waste contamination and surveillance (15min)             |
|               | Tom Wittum   |
|               | Professor  |
|               | Department of Veterinary Preventive Medicine                                     |
|               | The Ohio State University  |
|               | Case study presentation - Hospital waste contamination in India (15min)          |
|               | Zia Ahammad  |
|               | Professor  |
|               | Biochemical Engineering and Biotechnology  |
|               | IITD Dehli   |
|               | Discussion Panel (60min)   |
|               | Panellists: Zia Ahammad (IITD Delhi), Gary Garber (Public Health Ontario), David |
|               | Graham (Newcastle University), Christopher Hui (University of Hong Kong), Tom    |
|               | Wittum (Ohio State University)   |
| 10:15-10:45am | Break  |
|               | Location: East Meeting Rooms 11 and 12   |

| 10:45am-12:15pm | Session 2 - Contamination of the environment from animal waste  |
|-----------------|---|
|                 | Moderator: Kristy Buckley, Meridian Institute   |
|                 | Presentation – A global view of animal waste contamination (15min)  |
|                 | Ana Maria de Roda Husman  |
|                 | Laboratory for Zoonoses and Environmental Microbiology  |
|                 | Netherlands National Institute for Public Health and the Environment  |
|                 | Case study presentation – What are the tools to monitor and control contamination? (15min)                              |
|                 | Lisa Durso  |
|                 | Research Microbiologist   |
|                 | USDA  |
|                 | Discussion Panel (60min)  |
|                 | Panellists: Lisa Durso (USDA), Will Gaze (University of Exeter), JPS Gill (Guru   |
|                 | Angad Dev Veterinary and Animal Sciences University), Ana Maria de Roda   |
|                 | Husman (RIVM), Ed Topp (Agriculture and Agri-Food Canada), Dov Stekel (University of Nottingham)                        |
|                 | (Offiversity of Nottingham)   |
| 12:15-1:15pm    | Lunch   |
|                 | Location: East Mastina Pooms 11 and 13  |
|                 | Location: East Meeting Rooms 11 and 12  |
| 1:15-2:45pm     | Session 3 - Contamination of the environment from general sewage waste<br>Moderator: Kristy Buckley, Meridian Institute |
|                 | Presentation - Sewage waste contamination and surveillance (10min)  |
|                 | Jean McLain   |
|                 | Assistant Dean and Research Scientist   |
|                 | University of Arizona   |
|                 | Presentation – Municipal Wastewater Treatment Plants as a Hotspot for Environmental AMR (10min)                         |
|                 | Tong Zhang  |
|                 | Professor of Civil Engineering  |
|                 | The University of Hong Kong   |
|                 | Case study presentation - The risk to human health in different global contexts (10min)                                 |
|                 | Emily Poucham   |
|                 | Emily Rousham Senior Lecturer, Centre for Global Health and Human Development   |
|                 | Loughborough University   |
|                 | Discussion Panel (60min)  |

|             | Panellists: Tim LaPara (University of Minnesota) Jean McLain (University of Arizona), Joseph Oundo (Henry M Jackson Foundation Medical Research International), Emily Rousham (Loughborough University), Andrew Singer (NERC Centre for Ecology & Hydrology), Shashidhar Thatikonda (Indian Institute of Technology Hyderabad), Tong Zhang (University of Hong Kong). |
|-------------|---|
| 2:45-3:15pm | Break  Location: East Meeting Rooms 11 and 12   |
| 3:15-4:45pm | Session 4 - Strategies for measuring and mitigating environmental contamination of antimicrobials to reduce impact on human health Moderator: Kristy Buckley, Meridian Institute  |
|             | <b>Presentation</b> – Strategies for mitigating environmental contamination through water processing <b>(15min)</b>   |
|             | David Graham Professor of Ecosystems Engineering Newcastle University   |
|             | <b>Presentation</b> – Strategies for monitoring and surveillance of environmental contamination (15min)   |
|             | Andrew Singer Senior Scientist NERC Centre for Ecology & Hydrology  |
|             | Discussion Panel (75min) Panellists: David Graham (Newcastle University), Jean McLain (University of Arizona), Astrid Wester (WHO), Tom Wittum (Ohio State University), Cliff McDonald (Centers for Disease Control and Prevention), Andrew Singer (NERC Centre for Ecology & Hydrology)  |
| 4:45-5:00pm | Final Plenary/Wrap-up  Moderator: Kristy Buckley, Meridian Institute  |
| 6:00-8:00pm | Evening Reception   |
|             | Location: The Blackbird Public House and Oyster Bar (tentatively) 905 Dunsmuir St, Vancouver, BC V6C 1A8  |

| Thursday, April 5 |   |
|-------------------|---|
| 7:30-8:00am       | Light breakfast and coffee/tea  Location: East Meeting Rooms 11 and 12  |
| 8:00-8:10am       | Welcoming Remarks   |
|                   | Location: East Meeting rooms 8 and 15   |
|                   | Nicole Davison British Consul-General in Vancouver  |
| 8:10-8:30am       | Introduction to the day   |
|                   | Jean Patel Science Team Lead, Antibiotic Resistance Coordination and Strategy Unit Centers for Disease Control and Prevention   |
| 8:30-10:00am      | Session 5 - Antibiotic manufacturing waste in the environment  Moderator: Kristy Buckley, Meridian Institute  |
|                   | Case study presentation – Manufacturing waste contamination and surveillance (15min) Diana Aga  |
|                   | Professor of Chemistry & Director of Graduate Studies University of Buffalo   |
|                   | Case study presentation – Industry activity to mitigate environmental AMR (15min)   |
|                   | Damiano de Felice Director of Strategy  |
|                   | Access to Medicines Foundation  |
|                   | Discussion Panel (60min)  Panellists: Diana Aga (University of Buffalo), Damiano de Felice (Access to Medicines Foundation), Sumanth Gandra (Center for Disease Dynamics, Economics & Policy), Andrew Sweetman (Lancaster University), Nick Voulvoulis (Imperial College London), Ellen Kondracki (BD). |
| 10:00-10:30am     | Break   |
|                   | Location: East Meeting Rooms 11 and 12  |

| 10:30-12:00  | Session 6 – Antibiotic use as pesticides  Moderator: Kristy Buckley, Meridian Institute  |
|--------------|--|
|              | Presentation: Why and how are antibiotics used as pesticides? (15min)  |
|              | Virginia Stockwell  Plant Pathologist, Horticultural Crops Research Unit  U.S. Department of Agriculture (USDA)  |
|              | Presentation: Can antibiotic pesticides select for resistance that affects human health? (15min)   |
|              | Jeff LeJeune Food Safety and Quality Unit FAO  |
|              | Discussion Panel (60min) Stephane Bayen (McGill University), Karlyn Beer (Centers for Disease Control and Prevention), Susan Jennings (US Environmental Protection Agency, Office of Pesticide Programs), Jeff LeJeune (FAO), Jean Patel (Centers for Disease Control and Prevention), Virginia Stockwell (USDA) |
| 12:00-1:45pm | Lunch  Location: East Meeting Rooms 11 and 12  |
| 1:45-3:30pm  | Session 7 – What actions can we take now and where do barriers still exist?  Moderator: Kristy Buckley, Meridian Institute   |
|              | Presentation – Moving forward the environmental AMR policy agenda  |
|              | Jeremy Knox Policy and Advocacy Lead Wellcome Trust  |
|              | <ul> <li>Interactive group exercise</li> <li>What are the most compelling mitigation strategies and why?</li> <li>What can we act on now?</li> <li>Where do we need further information to take action?</li> </ul>   |
| 3:30-4:00pm  | Break  Location: East Meeting Rooms 11 and 12  |

# Multilateral Meeting on Environmental AMR, Vancouver Canada, April 4&5th

| 4:00-4:45pm | Final Reflections & Observations Panel  Moderator: Kristy Buckley, Meridian Institute   |
|-------------|---|
|             | Panellists: Tim Jinks (Wellcome Trust), Sharon Peacock (LSHTM), Lee Slater (Defra), Astrid Wester (WHO), Padmini Srikantiah (Gates), Michael Craig (Centers for Disease Control and Prevention), Rebecca Irwin (Public Health Agency of Canada) |
| 4:45-5:15pm | Final Plenary/Wrap-up   |
|             | Moderator: Kristy Buckley, Meridian Institute   |

# WELCOME TO THE

# INTERNATIONAL ENVIRONMENTAL AMR FORUM

# ADDRESS

# **Meeting Location**

Vancouver Convention Centre East

East Meeting Rooms 8 and 15 999 Canada Place Vancouver, B.C V6C 0C3



# **CONVENTION CENTRE**

The Vancouver Convention Centre is located in downtown Vancouver. For more information about the facility and transit option, visit: https://www.vancouverconventioncentre.com/



# TRANSPORTATION

The Vancouver International Airport is approximately 10 miles (16 km) from the Vancouver International Airport

- Taxi
- TransLink (public transportation): https://www.translink.ca/

# (2) MEALS PROVIDED

- Light breakfast and lunch will be provided on April 4 and 5
- An evening reception will be held from 6-8pm on April 4 at The Blackbird Public House and Oyster Bar
  - o 905 Dunsmuir St, Vancouver, BC V6C 1A8

From: Patel, Jean (CDC/OID/NCEZID) [vzp4@cdc.gov]

**Sent**: 2/15/2017 5:33:15 PM

To: Jennings, Susan [Jennings.Susan@epa.gov]

**Subject**: RE: joint statement **Attachments**: Joint Statement draft.docx

Can work on this today if needed.

From: Jennings, Susan [mailto:Jennings.Susan@epa.gov]

**Sent:** Wednesday, February 15, 2017 12:30 PM **To:** Patel, Jean (CDC/OID/NCEZID) <vzp4@cdc.gov>

Subject: joint statement

Hi Jean,

Can you send me whatever has been written on the joint statement?

Thanks,

Susan.

From: Raziano, Amanda J. (CDC/OID/NCEZID) [aqg3@cdc.gov]

**Sent**: 11/29/2017 10:20:59 PM

**To**: Jennings, Susan [Jennings.Susan@epa.gov]

**Subject**: RE: Azole-resistance follow up

Attachments: Antimicrob-resist-genes-NRSA-skv2.pptx

Hi Susan,

Thank you again for taking the time to connect yesterday and set me straight on who's on first on your side © Our fungal folks would love to reconnect with the SMEs on the last call to follow up on some of their data discussion as well as share a little bit about a BAA that was awarded for some additional work on azole resistance. There is a very brief description on our website (https://www.cdc.gov/drugresistance/solutions-initiative/innovations-to-slow-AR.html):

# University of Georgia Research Foundation, Inc.

Azole resistance in agricultural settings

Researchers will collect and characterize azole-resistant fungal strains from agricultural and horticultural sites. Azoles are used to protect crops from fungi, but azole-resistant fungi can infect people and cause disease that is difficult to treat and can lead to death.

I am checking on what else we can send to you for background and will follow up soon. Also, as discussed, I'm attaching slides from a presentation that he gave here at CDC in late July. Let me know if they don't come through and I'll try to convert to pdf.

After a quick scan of calendars, it looks like we have the most flexibility for a call on a Mon, Wed or Fri over the coming weeks. If there are dates/times you want to propose, I can look in more detail.

Thanks! Amanda

From: Jennings, Susan [mailto:Jennings.Susan@epa.gov]

Sent: Tuesday, November 28, 2017 9:15 AM

To: Giles-Parker, Cynthia <Giles-Parker.Cynthia@epa.gov>; Raziano, Amanda J. (CDC/OID/NCEZID) <aqg3@cdc.gov>

Subject: RE: Azole-resistance follow up

Yes, I would be happy to coordinate from our side. Are you available to talk about this sometime? I'm fairly available for the next couple of weeks, please feel free to suggest a time or give me a call.

Thanks,

Susan.

Susan Jennings Senior Advisor for Public Health Office of Pesticide Programs (706) 355-8574 (office) (703) 216-8627 (cell) From: Giles-Parker, Cynthia

Sent: Tuesday, November 28, 2017 9:12 AM

To: Raziano, Amanda J. (CDC/OID/NCEZID) <a href="mailto:agg3@cdc.gov">agg3@cdc.gov</a>

Cc: Jennings, Susan < Jennings.Susan@epa.gov>

Subject: RE: Azole-resistance follow up

Hello Amanda,

I have copied Susan Jennings on this email regarding your request for a meeting. Susan will be your contact on this topic. Hopefully, she will be able to coordinate a meeting between our agencies.

Regards, Cynthia

From: Raziano, Amanda J. (CDC/OID/NCEZID) [mailto:aqg3@cdc.gov]

Sent: Monday, November 27, 2017 3:38 PM

To: Giles-Parker, Cynthia < Giles-Parker. Cynthia@epa.gov>

Subject: RE: Azole-resistance follow up

Hello Cynthia,

I am following up on the email below to see if the folks we connected with earlier this year might be available for another call to discuss additional work around azole resistance. I hope you enjoyed the Thanksgiving holiday!

Best, Amanda

**From:** Raziano, Amanda J. (CDC/OID/NCEZID) **Sent:** Thursday, October 19, 2017 9:40 AM

To: Giles-Parker, Cynthia < Giles-Parker. Cynthia@epa.gov>

Cc: Jackson, Brendan R. (CDC/OID/NCEZID) < iyn0@cdc.gov>; Litvintseva, Anastasia P. (CDC/OID/NCEZID)

<frq8@cdc.gov>; Chiller, Tom (CDC/OID/NCEZID) <tnc3@cdc.gov>; Lockhart, Shawn (CDC/OID/NCEZID) <gyi2@cdc.gov>;

Sievert, Dawn M. (CDC/OID/NCEZID) <a href="mailto:sievert">alz1@cdc.gov</a>; Benjamin, Lynette E. (CDC/OID/NCEZID) <a href="mailto:sievert">bil0@cdc.gov</a>

Subject: Azole-resistance follow up

Good morning Cynthia,

I hope this email finds you well. We have been able to extend our work around azole resistance and fungicide use through another targeted project and wanted to see if there might be a good time to provide an update for those interested on your side.

Please let me know if there's a good date/time to reconnect.

Best, Amanda

From: Giles-Parker, Cynthia [mailto:Giles-Parker.Cynthia@epa.gov]

Sent: Wednesday, June 21, 2017 8:53 AM

To: Raziano, Amanda J. (CDC/OID/NCEZID) <aqg3@cdc.gov>

Cc: Jackson, Brendan R. (CDC/OID/NCEZID) < <a href="mailto:ivn0@cdc.gov">ivn0@cdc.gov</a>; Litvintseva, Anastasia P. (CDC/OID/NCEZID) < <a href="mailto:frq8@cdc.gov">frq8@cdc.gov</a>; Chiller, Tom (CDC/OID/NCEZID) < <a href="mailto:tnc3@cdc.gov">frq8@cdc.gov</a>; Lockhart, Shawn (CDC/OID/NCEZID) < <a href="mailto:gyi2@cdc.gov">gyi2@cdc.gov</a>> Subject: RE: Thank you!

Hello Amanda

Thanks for the additional information identified below. I have listed the participants on the call yesterday. There are a couple of items that we need to follow up on to continue our discussion on the azoles which I have also listed below:

Participants on call:

Cynthia Giles-Parker, Offices Pesticide Programs (OPP)/Registration Division (RD)/Fungicide Branch (FB) Rachel Holloman, OPP/RD/Fungicide Herbicide Branch Hope Johnson, OPP/RD/FB
Tony Kish, OPP/RD/FB
Susan Jennings, OPP/Immediate Office/Public Health Officer for OPP
Arnet Jones, OPP/Biological and Economic Analysis Division (BEAD)/Immediate Office
Tara Chandgoyal, OPP/BEAD/Biological Analysis Branch
Tracy Perry, OPP/Pesticide Re-evaluation Division (PRD)

# Action Items:

Search use information on registered conazoles. Try to provide non-confidential version of information Fungicide Resistance Action - check to see if any reports on pathogen resistance and Aspergillus resistance <a href="http://www.frac.info/">http://www.frac.info/</a>

USDA – query if any information on resistance in peanuts or other crops, make USDA aware of concern Search if USGS has any water information/monitoring on conazoles

Look forward to our continued discussions and next steps on this topic.

Cynthia

From: Raziano, Amanda J. (CDC/OID/NCEZID) [mailto:agg3@cdc.gov]

Sent: Tuesday, June 20, 2017 5:41 PM

To: Giles-Parker, Cynthia < Giles-Parker. Cynthia@epa.gov>

Cc: Jackson, Brendan R. (CDC/OID/NCEZID) <iyn0@cdc.gov>; Litvintseva, Anastasia P. (CDC/OID/NCEZID)

<frq8@cdc.gov>; Chiller, Tom (CDC/OID/NCEZID) <tnc3@cdc.gov>; Lockhart, Shawn (CDC/OID/NCEZID) <gyi2@cdc.gov>

Subject: Thank you!

Cynthia,

Thank you again for helping to facilitate the conversation today. It was very helpful to get feedback from your colleagues and we appreciate the offers for additional information sharing and future communications.

I wanted to be sure you had the names and contact information for our experts on the call today, including Shawn, our Fungal Reference Laboratory Director who wasn't able to join. Please feel free to share with those in your office as appropriate. If you are able to share a list of the folks on the call with us, we would appreciated it as well. We are happy to work through you or appropriate channels for communications, but I don't think we fully caught all the names and offices during the introductions.

Tom Chiller, MD MPH – Chief, Mycotic Diseases Branch, Division for Foodborne, Waterborne & Environmental Disease, National Center for Emerging and Zoonotic Infectious Diseases
Brendan Jackson, MD MPH – Deputy, Mycotic Diseases Branch, Division for Foodborne, Waterborne & Environmental Disease, National Center for Emerging and Zoonotic Infectious Diseases
Shawn R. Lockhart, PhD (ABMM) – Director, Fungal Reference Laboratory, Division for Foodborne, Waterborne & Environmental Disease, National Center for Emerging and Zoonotic Infectious Diseases
Anastasia Litvintseva, PhD – Lead, Fungal Research Team, Mycotic Diseases Branch, Division for Foodborne, Waterborne & Environmental Disease, National Center for Emerging and Zoonotic Infectious Diseases

We also wanted to share a couple additional references:

A link to information on the European CDC Risk Assessment for azole resistance in Aspergillus: <a href="http://ecdc.europa.eu/en/press/news/">http://ecdc.europa.eu/en/press/news/</a> layouts/forms/News DispForm.aspx?List=8db7286c-fe2d-476c-9133-18ff4cb1b568&ID=32

2015 invited article on azole resistance (attached): Verweij, PE. Azole resistance in *Aspergillus fumigatus:* can we retain clinical use of mold-active antifungal azoles? J Clin Infect Dis.

Best, Amanda

# Amanda Raziano MPH

Office of Strategic Communication, Policy, & Partnerships Division of Foodborne, Waterborne, and Environmental Disease National Center for Emerging and Zoonotic Infectious Diseases

Centers for Disease Control and Prevention 1600 Clifton Rd NE Atlanta, GA 30333 Mailstop C-09 Office Phone:404-639-7308 Fax: 404-639-2577

From: Patel, Jean (CDC/OID/NCEZID) [vzp4@cdc.gov]

**Sent**: 6/20/2017 4:15:34 PM

To: Jennings, Susan [Jennings.Susan@epa.gov]

CC: Craig, Michael R. (CDC/OID/NCEZID) [bez7@cdc.gov]

Subject: CDC Report

Attachments: CDC Report Streptomycin and Oxytetracycline Resistance Human Pathogens.pdf

Susan

Thank you for sheparding the MOU. I am happy that it is signed.

Attached is the report. Please send any questions from EPA.

Jean

From: Harbottle, Heather [Heather.Harbottle@fda.hhs.gov]

**Sent**: 3/19/2018 4:03:10 PM

To: Jennings, Susan [Jennings.Susan@epa.gov]; Carl Schultze [Carl.P.Schulze@aphis.usda.gov]; Julius Fajardo

[Julius.Fajardo@ARS.USDA.GOV]; Patel, Jean (CDC) [vzp4@cdc.gov]; Gilbert, Jeffrey M [Jeff.Gilbert@fda.hhs.gov];

Craig, Michael R (CDC) [bez7@cdc.gov]; Rose Hammond [Rose.Hammond@ARS.USDA.GOV]

**Subject**: RE: Meeting?

Hi Susan, I'm flexible on those dates. Thanks! Heather

From: Jennings, Susan [mailto:Jennings.Susan@epa.gov]

Sent: Monday, March 19, 2018 11:55 AM

**To:** Carl Schultze <Carl.P.Schulze@aphis.usda.gov>; Julius Fajardo <Julius.Fajardo@ARS.USDA.GOV>; Harbottle, Heather <Heather.Harbottle@fda.hhs.gov>; Patel, Jean (CDC) <vzp4@cdc.gov>; Gilbert, Jeffrey M <Jeff.Gilbert@fda.hhs.gov>;

Craig, Michael R (CDC) <br/>
<br/>
dez7@cdc.gov>; Rose Hammond <Rose.Hammond@ARS.USDA.GOV>

Subject: Meeting?

Hi all,

We are about to start working on the registration review of streptomycin and oxytetracycline. As you may recall from our earlier meeting, this process is a review of existing labels and uses. Some uses that we've discussed include homeowner uses and application by air.

I will be travelling to DC the week of May 7<sup>th</sup> and was hoping that we might be able to have a face-to-face meeting on the 9<sup>th</sup> or 10<sup>th</sup>, at least for those of you who are in town? Maybe a half-day or a bit longer? We haven't met for a while and it would be a good chance to regroup and rethink our approach to these compounds, especially in light of what we have learned from the recent new uses.

Please let me know if you think you will be available.

Thanks,

Susan.

Susan Jennings Senior Advisor for Public Health Office of Pesticide Programs (706) 355-8574 (office) (703) 216-8627 (cell)

From: Jennings, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B3E06D481ADC45F296232CF2DE82A8B7-JENNINGS, SUSAN]

**Sent**: 11/16/2018 6:48:27 PM **To**: Jean Patel [vzp4@cdc.gov]

CC: Thaker, Kaytna (CDC/DDID/NCEZID/DHQP) (CTR) [xxb4@cdc.gov]

**Subject**: FW: Most recent AR in the environment draft

Attachments: AMR Env Forum Report combined\_11016018\_MS.docx

Jean,

Attached are Mark's responses. If you want to discuss, please let me know. The earlier the better.

Thanks,

Susan.

From: Jennings, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B3E06D481ADC45F296232CF2DE82A8B7-JENNINGS, SUSAN]

**Sent**: 11/14/2018 2:03:51 PM **To**: Jean Patel [vzp4@cdc.gov]

CC: Suarez, Mark [Suarez.Mark@epa.gov]
Subject: FW: Most recent AR in the environment draft

Attachments: AMR Env Forum Report combined\_11012018\_MS.docx

Jean,

See the attached comments, particularly on the usage section, from Mark.

Thanks,

Susan.

From: Suarez, Mark

Sent: Tuesday, November 13, 2018 6:00 PM

To: Jennings, Susan < Jennings. Susan@epa.gov>

Subject: RE: Most recent AR in the environment draft

### **Deliberative Process / Ex. 5**

Let me know, if you'd like to discuss it.

Regards, Mark

Mark Suarez
Entomologist
Science Information and Analysis Branch
Biological and Economic Analysis Division
US EPA (Mail Code 7503P)
1200 Pennsylvania Avenue, NW
Washington, DC 20460

phone: 703-305-0120

From: Jennings, Susan

**Sent:** Tuesday, November 13, 2018 12:19 PM **To:** Suarez, Mark <Suarez, Mark@epa.gov>

Subject: Re: Most recent AR in the environment draft

Maybe just check that they made your earlier comments?

On Nov 13, 2018, at 12:17 PM, Suarez, Mark <Suarez. Mark@epa.gov> wrote:

Susan,

I did want to give another once through. I'll make comments by COB.

Regards, Mark

Mark Suarez
Entomologist
Science Information and Analysis Branch
Biological and Economic Analysis Division
US EPA (Mail Code 7503P)
1200 Pennsylvania Avenue, NW
Washington, DC 20460

phone: 703-305-0120

From: Jennings, Susan

**Sent:** Tuesday, November 13, 2018 11:31 AM **To:** Suarez, Mark < <u>Suarez, Mark@epa.gov</u>>

**Subject:** Most recent AR in the environment draft

Hi Mark,

Are you planning to comment on this most recent version? If you haven't looked into it yet, I wouldn't worry about it. I skimmed it and it looked ok.

Thanks,

SUsan.

From: Jennings, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B3E06D481ADC45F296232CF2DE82A8B7-JENNINGS, SUSAN]

**Sent**: 9/6/2018 6:13:01 PM

To: Patel, Jean (CDC/OID/NCEZID) [vzp4@cdc.gov]; Craig, Michael R. (CDC/OID/NCEZID) [bez7@cdc.gov]; Pantino,

Elizabeth (CDC/OID/NCEZID) [ymt0@cdc.gov]

CC: Suarez, Mark [Suarez.Mark@epa.gov]
Subject: RE: Resolving the EPA comments

Attachments: AMR Env Forum Report combined\_083118 EPA Pesticide Comments (004).docx

Small adjustments to p. 65 in the attached. I'm fine with your changes on p. 68 and it's good as is.

Thanks again for working with us on these and please let me know if there's anything else we can do to help.

Susan.

----Original Appointment----

From: Patel, Jean (CDC/OID/NCEZID) [mailto:vzp4@cdc.gov]

Sent: Wednesday, September 05, 2018 8:57 AM

To: Patel, Jean (CDC/OID/NCEZID); Craig, Michael R. (CDC/OID/NCEZID); Pantino, Elizabeth (CDC/OID/NCEZID); Jennings,

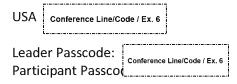
Susan

Subject: Resolving the EPA comments

When: Thursday, September 06, 2018 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: Teleconference

Susan – please forward to Mike.



#### Appointment

From: Jennings, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B3E06D481ADC45F296232CF2DE82A8B7-JENNINGS, SUSAN]

**Sent**: 9/6/2018 2:10:59 PM

To: Suarez, Mark [Suarez.Mark@epa.gov]

**Subject**: FW: Resolving the EPA comments

Attachments: AMR Env Forum Report combined\_083118 EPA Pesticide Comments.docx

**Location**: Teleconference

**Start**: 9/6/2018 5:00:00 PM **End**: 9/6/2018 6:00:00 PM

Show Time As: Tentative

-----Original Appointment-----

From: Patel, Jean (CDC/OID/NCEZID) [mailto:vzp4@cdc.gov]

Sent: Wednesday, September 05, 2018 8:57 AM

To: Patel, Jean (CDC/OID/NCEZID); Craig, Michael R. (CDC/OID/NCEZID); Pantino, Elizabeth (CDC/OID/NCEZID); Jennings,

Susan

Subject: Resolving the EPA comments

When: Thursday, September 06, 2018 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: Teleconference

Susan – please forward to Mike.

USA Conference Line/Code / Ex. 6

Leader Passcode: Conference Line/Code / E
Participant Passcod

#### Appointment

From: Jennings, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B3E06D481ADC45F296232CF2DE82A8B7-JENNINGS, SUSAN]

**Sent**: 9/5/2018 7:17:06 PM

To: Suarez, Mark [Suarez.Mark@epa.gov]

**Subject**: FW: Resolving the EPA comments

Attachments: AMR Env Forum Report combined\_083118 EPA Pesticide Comments.docx

**Location**: Teleconference

**Start**: 9/6/2018 5:00:00 PM **End**: 9/6/2018 6:00:00 PM

Show Time As: Tentative

-----Original Appointment-----

From: Patel, Jean (CDC/OID/NCEZID) [mailto:vzp4@cdc.gov]

Sent: Wednesday, September 05, 2018 8:57 AM

To: Patel, Jean (CDC/OID/NCEZID); Craig, Michael R. (CDC/OID/NCEZID); Pantino, Elizabeth (CDC/OID/NCEZID); Jennings,

Susan

Subject: Resolving the EPA comments

When: Thursday, September 06, 2018 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: Teleconference

Susan – please forward.

USA Conference Line/Code / Ex. 6

Leader Passcode:

Participant Passcod

ED\_002697\_00060047-00001

From: Jennings, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B3E06D481ADC45F296232CF2DE82A8B7-JENNINGS, SUSAN]

**Sent**: 9/4/2018 5:31:12 PM **To**: Jean Patel [vzp4@cdc.gov]

**CC**: sgumbis@cdc.gov; thenning@cdc.gov

**Subject**: EPA's response to CDC's response to comments for the AMR report **Attachments**: AMR Env Forum Report combined\_083118 EPA Pesticide Comments.docx

Hi,

Attached is EPA's response to your inclusion of our comments. Please let me know if there are any issues and I'd be happy to set up a call to discuss anything that is unclear.

Thanks,

Susan.

Susan Jennings Senior Advisor for Public Health Office of Pesticide Programs (706) 355-8574 (office) (703) 216-8627 (cell)

Thanks,

Susan.

From: Jennings, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B3E06D481ADC45F296232CF2DE82A8B7-JENNINGS, SUSAN]

**Sent**: 5/25/2017 3:37:51 PM **To**: Jean Patel [vzp4@cdc.gov]

Subject: MOU attached

Attachments: CDC antibacterial resistance MOU 05-25-17 final.docx

Hi Jean,

Attached is the MOU in Word format. I've changed the EPA signature block and you'll want to do the same for the CDC block.

Once it comes back with the CDC signature, then we'll route on our end.

Thanks,

Susan.

From: Jennings, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B3E06D481ADC45F296232CF2DE82A8B7-JENNINGS, SUSAN]

Sent: 5/19/2017 6:20:47 PM

To: Jean Patel [vzp4@cdc.gov]

Subject: FW: antibiotic resistance MOU

Attachments: CDC antibacterial resistance MOU 05-18-17.sbg.docx

Couple of small changes at the end.

Elevating a bit at our OGC.

Shooting to get this signed on Monday.

Thanks.

From: Jennings, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B3E06D481ADC45F296232CF2DE82A8B7-JENNINGS, SUSAN]

**Sent**: 5/18/2017 4:03:44 PM

**To**: Patel, Jean (CDC/OID/NCEZID) [vzp4@cdc.gov]

Subject: RE: MOU

Attachments: CDC antibacterial resistance MOU 05-18-17.docx

Great. Attached is a version with the right signature. Our OGC has provided comments, but our management is asking for their official concurrence. Not sure what this means on a timeline perspective. I'll let you know as soon as I do, but unless you hear differently, the attached is the most recent.

#### Thanks!

From: Patel, Jean (CDC/OID/NCEZID) [mailto:vzp4@cdc.gov]

Sent: Thursday, May 18, 2017 11:58 AM

To: Jennings, Susan < Jennings.Susan@epa.gov>

Subject: MOU

This is good to go on our end. Can you please add the name of the EPA person signing? Do you want to sign first and then CDC (doesn't matter to me).

Jean

From: Jennings, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B3E06D481ADC45F296232CF2DE82A8B7-JENNINGS, SUSAN]

**Sent**: 5/11/2017 1:47:07 PM **To**: Jean Patel [vzp4@cdc.gov]

Subject: MOU

Attachments: CDC antibacterial resistance MOU 05-11-17.sbg.docx

Hi Jean,

Attached is the most recent draft of the MOU. I can't share it with our OD until Monday. If you want to look it over (there have been some changes) and see if you have any changes to our changes. If I incorporate before Monday then I'll just send Rick the revised version.

Thanks,

Susan.

From: Jennings, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B3E06D481ADC45F296232CF2DE82A8B7-JENNINGS, SUSAN]

**Sent**: 4/4/2017 2:26:18 PM

**To**: Patel, Jean (CDC/OID/NCEZID) [vzp4@cdc.gov]

**Subject**: RE: Isolate testing results

Thanks!!

From: Patel, Jean (CDC/OID/NCEZID) [mailto:vzp4@cdc.gov]

Sent: Tuesday, April 04, 2017 10:24 AM

To: Jennings, Susan < Jennings.Susan@epa.gov>

Subject: Isolate testing results

Susan – please use this for internal purposes only. At the request of EPA, CDC conducted an in vitro antimicrobial susceptibility study. Details below:

## **Deliberative Process / Ex. 5**

# **Deliberative Process / Ex. 5**

Discussion (not done)

From: Jennings, Susan [Jennings.Susan@epa.gov]

**Sent**: 2/25/2017 12:16:25 AM

To: Patel, Jean (CDC/OID/NCEZID) [vzp4@cdc.gov]

Subject: Re: AST testing

Ok, thanks for it all. This will be fine. I thought the panel was different for the two drugs, but guess I was wrong 2

Have a good weekend,

Susan.

On Feb 24, 2017, at 7:13 PM, Patel, Jean (CDC/OID/NCEZID) <vzp4@cdc.gov> wrote:

Yes

From: Jennings, Susan < Jennings.Susan@epa.gov > Date: February 24, 2017 at 7:05:05 PM EST

To: Patel, Jean (CDC/OID/NCEZID) <vzp4@cdc.gov>

Subject: Re: AST testing

So the panel is the same for both drugs?

Susan.

On Feb 24, 2017, at 4:47 PM, Patel, Jean (CDC/OID/NCEZID) < vzp4@cdc.gov> wrote:

HI Susan

I hope this helps. Let me know if it doesn't make sense...

### **Deliberative Process / Ex. 5**

Jean

From: Jennings, Susan [mailto:Jennings.Susan@epa.gov]

Sent: Thursday, February 23, 2017 3:30 PM

To: Patel, Jean (CDC/OID/NCEZID) < vzp4@cdc.gov>
Cc: Craig, Michael R. (CDC/OID/NCEZID) < bez7@cdc.gov>

Subject: RE: AST testing

Yes, that would be great.

Do you have a quick paragraph or so on what these tests are and how they will be conducted (broad/general terms)? I'm getting a lot of questions so it would be easier if there was a direct quote.

Thanks for all your help on this,

SUsan.

From: Patel, Jean (CDC/OID/NCEZID) [mailto:vzp4@cdc.gov]

**Sent:** Thursday, February 23, 2017 2:58 PM **To:** Jennings, Susan < Jennings, Susan@epa.gov>

Cc: Craig, Michael R. (CDC/OID/NCEZID) < bez7@cdc.gov>

Subject: AST testing

Susan

We can get you the results of the antimicrobial susceptibility testing by March 24<sup>th</sup>. Would this work?

Will send a draft MOU early next week.

#### Jean B. Patel, PhD, D(ABMM)

Antimicrobial Resistance Coordination & Strategy
Division of Healthcare Quality Promotion (DHQP)
National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)
Centers for Disease Control and Prevention — Atlanta, GA
OFFICE: 404.639.0361 | jpatel1@cdc.gov

From: Jennings, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B3E06D481ADC45F296232CF2DE82A8B7-JENNINGS, SUSAN]

Sent: 8/31/2018 2:01:21 PM

To: Jean Patel [vzp4@cdc.gov]

Subject: EPA response to AMR Document

Attachments: AMR Env Forum Report combined\_080818 Clearance Edits.docx

Hi Jean,

Attached are EPA's official comments on the AMR document. Our AA has asked if there is a process for ensuring these comments are incorporated or responded to? Could you please send us the most recent document with the responses to EPA's comments?

I also wanted to remind you about changing "Environmental Protection Division" to "... Agency" for both Jay Gardner and Sharron Nappier. Also add "Office of Research and Development" to Jay and "Office of Water" to Sharron.

Thanks for all your patience with this,

Susan.

Susan Jennings Senior Advisor for Public Health Office of Pesticide Programs (706) 355-8574 (office) (703) 216-8627 (cell)

From: Jennings, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B3E06D481ADC45F296232CF2DE82A8B7-JENNINGS, SUSAN]

**Sent**: 8/27/2018 11:43:03 AM **To**: Jean Patel [vzp4@cdc.gov]

Subject: FW: Draft of Environmental AMR Report - Time Sensitive Response by 8/23

Attachments: AMR Env Forum Report combined\_080818 Clearance Edits.docx

Jean,

This is the version that we are sending to the AA for approval. I don't expect there to be too many changes from this one, but I'll let you know once it is approved.

Good luck,

Susan.

From: Jennings, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B3E06D481ADC45F296232CF2DE82A8B7-JENNINGS, SUSAN]

**Sent**: 8/23/2018 6:21:30 PM

**To**: Patel, Jean (CDC/OID/NCEZID) [vzp4@cdc.gov]

**Subject**: RE: Updated Environmental Report

Attachments: AMR Env Forum Report combined 080818 Clearance Edits.docx

Here is what we have so far. I haven't even read through them yet, but it should give you an idea about what we're thinking.

Susan.

From: Patel, Jean (CDC/OID/NCEZID) [mailto:vzp4@cdc.gov]

Sent: Thursday, August 23, 2018 1:44 PM

To: Jennings, Susan < Jennings.Susan@epa.gov>

Subject: Updated Environmental Report

I will include EPA comments when you have those ready. This version includes revisions based upon comments already received by CDC.

Thanks,

Jean

Jean B. Patel PhD, D(ABMM)
Science Team Lead
Antibiotic Resistance Coordination & Strategy
NCEZID/DHQP/OD
404.639.0361 | jpatel1@cdc.gov

From: Jennings, Susan [Jennings.Susan@epa.gov]

**Sent**: 3/9/2016 2:57:18 PM

To: Craig, Michael R. (CDC/OID/NCEZID) [bez7@cdc.gov]

Subject: Re: Follow-up: Streptomycin and Oxytetracycline pesticide requests pending with EPA

Personal Phone / Ex. 6 Or I can call you.

Sent from my iPhone

On Mar 9, 2016, at 9:40 AM, Craig, Michael R. (CDC/OID/NCEZID) <bez7@cdc.gov> wrote:

What number should I call?

From: Jennings, Susan [mailto:Jennings.Susan@epa.gov]

Sent: Wednesday, March 09, 2016 9:30 AM

To: Craig, Michael R. (CDC/OID/NCEZID) < bez7@cdc.gov>

Subject: Re: Follow-up: Streptomycin and Oxytetracycline pesticide requests pending with EPA

Ok, noon works. Talk to you then.

Sent from my iPhone

On Mar 9, 2016, at 9:20 AM, Craig, Michael R. (CDC/OID/NCEZID) < bez7@cdc.gov> wrote:

I have a conflict then but can do noon.

From: Jennings, Susan [mailto:Jennings.Susan@epa.gov]

Sent: Wednesday, March 09, 2016 9:15 AM

To: Craig, Michael R. (CDC/OID/NCEZID) < bez7@cdc.gov>

Subject: Re: Follow-up: Streptomycin and Oxytetracycline pesticide requests pending

with EPA

Would 11 work?

Sent from my iPhone

On Mar 9, 2016, at 8:55 AM, Craig, Michael R. (CDC/OID/NCEZID) < <a href="mailto:bez7@cdc.gov">bez7@cdc.gov</a> wrote:

Sure, what time?

From: Jennings, Susan [mailto:Jennings.Susan@epa.gov]

Sent: Wednesday, March 09, 2016 8:54 AM

To: Craig, Michael R. (CDC/OID/NCEZID) < bez7@cdc.gov>

Subject: Re: Follow-up: Streptomycin and Oxytetracycline pesticide

requests pending with EPA

Can we do tomorrow am instead?

Sent from my iPhone

On Mar 9, 2016, at 8:45 AM, Craig, Michael R. (CDC/OID/NCEZID) < bez7@cdc.gov > wrote:

Do you have time to discuss later today?

From: Jennings, Susan

[mailto:Jennings.Susan@epa.gov]

**Sent:** Wednesday, March 09, 2016 7:47 AM **To:** Hill, Shaunta < Hill. Shaunta@epa.gov > **Cc:** Craig, Michael R. (CDC/OID/NCEZID)

<<u>bez7@cdc.gov</u>>; Patel, Jean (CDC/OID/NCEZID) <<u>vzp4@cdc.gov</u>>; Wan, Ellen (CDC/OID/NCEZID)

<gqj0@cdc.gov>; Maignan, Tawanda

< Maignan. Tawanda@epa.gov>; Madden, Barbara

<Madden.Barbara@epa.gov>; Rosenblatt, Daniel

<Rosenblatt.Dan@epa.gov>; Lewis, Susan

<Lewis.Susan@epa.gov>

Subject: Re: Follow-up: Streptomycin and

Oxytetracycline pesticide requests pending with EPA

Hi,

#### **Deliberative Process / Ex. 5**

Thanks again,

Susan.

Sent from my iPhone

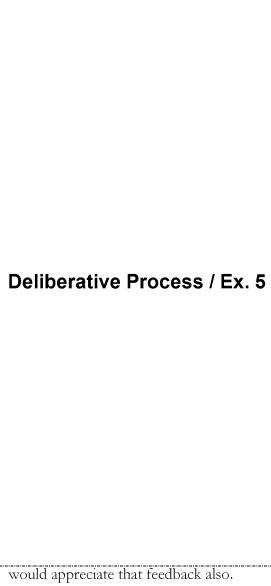
On Mar 8, 2016, at 2:36 PM, Hill, Shaunta < Hill.Shaunta@epa.gov > wrote:

HI Michael -

I just received CDC's feedback on the FL-Section 18 request. Thank you for noting that.

We are still looking to finalize the 2/10/16 meeting minutes (attached). Comments were received from FDA.

If its appropriate, Deliberative Process / Ex. 5



would appreciate that feedback also Please let me know if you have additional questions.

Regards,
\*\*\*\*\*\*\*\*\*\*\*\*\*\*
\*\*\*\*\*\*\*\*\*\*\*\*\*

Shaunta Hill-Hammond, Ph. D.
Plant Pathologist

U.S. EPA: Office of Chemical Safety and Pollution Prevention Registration Division/Fungicide Branch (PYS) 1200 Pennsylvania Avenue, NW (7505P) Washington, DC 20460

Tel: 703.347.8961 1 Fax: 703.305.6920

E-mail: hill.shaunta@epa.gov

From: Craig, Michael R. (CDC/OID/NCEZID)
[mailto:bez7@cdc.gov]

Sent: Tuesday, March 08, 2016 2:16 PM

To: Hill, Shaunta

<hackliner <a href="mailto:right-square">hill.Shaunta@epa.gov>; Patel, Jean (CDC/OID/NCEZID) <a href="mailto:vzp4@cdc.gov">vzp4@cdc.gov</a>; Wan, Ellen (CDC/OID/NCEZID)

<gqi0@cdc.gov> Cc: Jennings, Susan

<Jennings.Susan@epa.gov>

**Subject:** RE: Follow-up: Streptomycin and Oxytetracycline pesticide requests

pending with EPA

#### Shaunta:

Thanks for your email. We have been working with Susan and Tawanda on the emergency request from Florida and provided comments to Tawanda yesterday on potential mitigation steps.

Given the developments since our call last month, can you clarify the need for the updated minutes? It seems like some of the issues may now be moot.

Thank you, Michael

From: Hill, Shaunta

[mailto:Hill.Shaunta@epa.gov]

Sent: Tuesday, March 08, 2016 2:06 PM To: Patel, Jean (CDC/OID/NCEZID) < vzp4@cdc.gov>; Craig, Michael R. (CDC/OID/NCEZID) < bez7@cdc.gov>; Wan, Ellen (CDC/OID/NCEZID)

<gqi0@cdc.gov>

**Subject:** RE: Follow-up: Streptomycin and Oxytetracycline pesticide requests pending with EPA

Hello everyoneI just wanted to circle back on the meeting minutes from our teleconference last month.
We would greatly appreciate CDC's comments this week if possible.
Thank you

#### Regards,

\*\*\*\*\*\*\*\*\*\*\*\*\*\*

Shaunta Hill-Hammond, Ph. D.
Plant Pathologist
U.S. EPA: Office of Chemical Safety and
Pollution Prevention
Registration Division/Fungicide Branch
(PYS)
1200 Pennsylvania Avenue, NW (7505P)
Washington, DC 20460

Tel: 703.347.8961 1 Fax: 703.305.6920 E-mail: hill.shaunta@epa.gov

From: Hill, Shaunta

[mailto:Hill.Shaunta@epa.gov] **Sent:** Thursday, February 25, 2016

1:38 PM

**To:** Patel, Jean (CDC); Craig, Michael R (CDC); Harbottle, Heather; Gilbert,

Jeffrey M

**Cc:** Jennings, Susan; Kough, John; Chandgoyal, Tara; Hicks, Karen **Subject:** Follow-up: Streptomycin and Oxytetracycline pesticide requests

pending with EPA

Good Afternoon Everyone, Thank you for participating in the teleconference on Feb 10, 2016. As promised, I am following-up with the group to share the draft meeting minutes. I would greatly appreciate your review of the minutes and any comments/corrections you find by 3/3/16.

I am also providing the 152 review for the proposed Florida – citrus Section 18

request. Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

**Deliberative Process / Ex. 5** 

## The proposed meeting times are:

- Tuesday March 8, 9 am
- Thursday March 10, 1 pm
- Wednesday March 16,
   1 pm

Thank you and enjoy the rest of your day.

Regards,
\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*
\*\*\*\*\*\*\*\*\*\*\*\*\*

Shaunta Hill-Hammond, Ph. D.

Plant Pathologist

U.S. EPA: Office of Chemical Safety and Pollution Prevention

Registration Division/Fungicide Branch (PYS)

1200 Pennsylvania Avenue, NW (7505P) Washington, DC 20460

Tel: 703.347.8961 1 Fax: 703.305.6920

E-mail: hill.shaunta@epa.gov

<Meeting minutes\_02102016\_EPA-CDC-FDA\_antibiotics.docx> From: Jennings, Susan [Jennings.Susan@epa.gov]

**Sent**: 3/9/2016 1:54:21 PM

To: Craig, Michael R. (CDC/OID/NCEZID) [bez7@cdc.gov]

Subject: Re: Follow-up: Streptomycin and Oxytetracycline pesticide requests pending with EPA

Can we do tomorrow am instead?

Sent from my iPhone

On Mar 9, 2016, at 8:45 AM, Craig, Michael R. (CDC/OID/NCEZID) <bez7@cdc.gov> wrote:

Do you have time to discuss later today?

From: Jennings, Susan [mailto:Jennings.Susan@epa.gov]

**Sent:** Wednesday, March 09, 2016 7:47 AM **To:** Hill, Shaunta@epa.gov>

Cc: Craig, Michael R. (CDC/OID/NCEZID) < bez7@cdc.gov>; Patel, Jean (CDC/OID/NCEZID) < vzp4@cdc.gov>; Wan, Ellen (CDC/OID/NCEZID) < gi0@cdc.gov>; Maignan, Tawanda

< Maignan. Tawanda@epa.gov >; Madden, Barbara < Madden. Barbara@epa.gov >; Rosenblatt, Daniel

<Rosenblatt.Dan@epa.gov>; Lewis, Susan <Lewis.Susan@epa.gov>

Subject: Re: Follow-up: Streptomycin and Oxytetracycline pesticide requests pending with EPA

Hi,

### **Deliberative Process / Ex. 5**

Thanks again,

Susan.

Sent from my iPhone

On Mar 8, 2016, at 2:36 PM, Hill, Shaunta <Hill.Shaunta@epa.gov> wrote:

HI Michael –

I just received CDC's feedback on the FL-Section 18 request. Thank you for noting that.

We are still looking to finalize the 2/10/16 meeting minutes (attached). Comments were received from FDA.

### **Deliberative Process / Ex. 5**

proposed Section 3, we would appreciate that feedback also. Please let me know if you have additional questions.

#### Regards,

\*

Shaunta Hill-Hammond, Ph. D.

Plant Pathologist

U.S. EPA: Office of Chemical Safety and Pollution Prevention

Registration Division/Fungicide Branch (PYS)

1200 Pennsylvania Avenue, NW (7505P)

Washington, DC 20460

Tel: 703.347.8961 1 Fax: 703.305.6920

E-mail: hill.shaunta@epa.gov

From: Craig, Michael R. (CDC/OID/NCEZID) [mailto:bez7@cdc.gov]

**Sent:** Tuesday, March 08, 2016 2:16 PM

**To:** Hill, Shaunta < Hill. Shaunta@epa.gov >; Patel, Jean (CDC/OID/NCEZID)

<vzp4@cdc.gov>; Wan, Ellen (CDC/OID/NCEZID) <ggi0@cdc.gov>

Cc: Jennings, Susan < Jennings. Susan@epa.gov>

Subject: RE: Follow-up: Streptomycin and Oxytetracycline pesticide requests pending

with EPA

#### Shaunta:

Thanks for your email. We have been working with Susan and Tawanda on the emergency request from Florida and provided comments to Tawanda yesterday on potential mitigation steps.

Given the developments since our call last month, can you clarify the need for the updated minutes? It seems like some of the issues may now be moot.

Thank you, Michael From: Hill, Shaunta [mailto:Hill.Shaunta@epa.gov]

Sent: Tuesday, March 08, 2016 2:06 PM

**To:** Patel, Jean (CDC/OID/NCEZID) < vzp4@cdc.gov>; Craig, Michael R. (CDC/OID/NCEZID)

<br/><bez7@cdc.gov>; Wan, Ellen (CDC/OID/NCEZID) <gqj0@cdc.gov>

Subject: RE: Follow-up: Streptomycin and Oxytetracycline pesticide requests pending

with EPA

Hello everyone-

I just wanted to circle back on the meeting minutes from our teleconference last month.

We would greatly appreciate CDC's comments this week if possible.

Thank you

Regards,

Shaunta Hill-Hammond, Ph. D.

Plant Pathologist

U.S. EPA: Office of Chemical Safety and Pollution Prevention

Registration Division/Fungicide Branch (PYS)

1200 Pennsylvania Avenue, NW (7505P)

Washington, DC 20460

Tel: 703.347.8961 1 Fax: 703.305.6920

E-mail: hill.shaunta@epa.gov

From: Hill, Shaunta [mailto:Hill.Shaunta@epa.gov]

Sent: Thursday, February 25, 2016 1:38 PM

To: Patel, Jean (CDC); Craig, Michael R (CDC); Harbottle, Heather; Gilbert, Jeffrey M

Cc: Jennings, Susan; Kough, John; Chandgoyal, Tara; Hicks, Karen

Subject: Follow-up: Streptomycin and Oxytetracycline pesticide requests pending with

EPA

Good Afternoon Everyone,

Thank you for participating in the teleconference on Feb 10, 2016. As promised, I am following-up with the group to share the draft meeting minutes. I would greatly appreciate your review of the minutes and any comments/corrections you find by 3/3/16.

### **Deliberative Process / Ex. 5**

#### The proposed meeting times are:

Tuesday – March 8, 9 am

- Thursday March 10, 1 pm
- Wednesday March 16, 1 pm

#### Thank you and enjoy the rest of your day.

Regards,

\*\*\*\*\*\*\*\*\*\*\*\*\*\*

Shaunta Hill-Hammond, Ph. D.

Plant Pathologist

U.S. EPA: Office of Chemical Safety and Pollution Prevention

Registration Division/Fungicide Branch (PYS)

1200 Pennsylvania Avenue, NW (7505P)

Washington, DC 20460

Tel: 703.347.8961 1 Fax: 703.305.6920

E-mail: hill.shaunta@epa.gov

<Meeting minutes\_02102016\_EPA-CDC-FDA\_antibiotics.docx>

From: Jennings, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B3E06D481ADC45F296232CF2DE82A8B7-JENNINGS, SUSAN]

**Sent**: 3/7/2016 7:25:02 PM

To: Craig, Michael R. (CDC/OID/NCEZID) [bez7@cdc.gov]; Jean Patel [vzp4@cdc.gov]

**Subject**: FW: Florida Citrus Greening S18 for Antibiotics

Importance: High

I think you told Tawanda that you would get back to her on the email below? If you could cc: me on the response, I'd appreciate it.

Thanks,

Susan.

From: Maignan, Tawanda

Sent: Thursday, March 03, 2016 6:11 PM

To: bez7@cdc.gov

Cc: Jennings, Susan <Jennings.Susan@epa.gov>; Madden, Barbara <Madden.Barbara@epa.gov>; Rosenblatt, Daniel

<Rosenblatt.Dan@epa.gov>; Herndon, George <Herndon.George@epa.gov>

Subject: Florida Citrus Greening S18 for Antibiotics

Importance: High

Dr. Craig,

Again, thank you for taking the time to speak with use today and offer additional clarification on CDC's position with respect to the Section 18 for antibiotics and other uses. As discussed, we would like CDC's assistance/guidance with the type of monitoring we would like for Florida to conduct. For consideration, the following is a general summary that was provided by EPA's 152 Team on monitoring:

## **Deliberative Process / Ex. 5**

## **Deliberative Process / Ex. 5**

We look forward to your feedback and the contact information for Ms. Beth Bell at your earliest convenience.

Regards, Tawanda

Tawanda Maignan
Emergency Response Team Leader
Registration Division | Office of Pesticide Programs
Office of Chemical Safety & Pollution Prevention
U.S. Environmental Protection Agency (7505P)
1200 Pennsylvania Avenue, NW | Washington, DC 20460
Tel: (703) 308-8050 | Maignan. Tawanda@epa.gov

From: Jennings, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B3E06D481ADC45F296232CF2DE82A8B7-JENNINGS, SUSAN]

**Sent**: 3/7/2016 7:01:11 PM

To: Craig, Michael R. (CDC/OID/NCEZID) [bez7@cdc.gov]
CC: Patel, Jean (CDC/OID/NCEZID) [vzp4@cdc.gov]

Subject: RE: Florida Citrus Greening Situation

### **Deliberative Process / Ex. 5**

Thanks again,

Susan.

From: Craig, Michael R. (CDC/OID/NCEZID) [mailto:bez7@cdc.gov]

Sent: Monday, March 07, 2016 11:30 AMTo: Jennings, Susan < Jennings.Susan@epa.gov>Cc: Patel, Jean (CDC/OID/NCEZID) < vzp4@cdc.gov>Subject: RE: Florida Citrus Greening Situation

Thank you Susan. Do you need anything else from us right now?

Best, MC

From: Jennings, Susan [mailto:Jennings.Susan@epa.gov]

Sent: Monday, March 07, 2016 11:22 AM

To: Craig, Michael R. (CDC/OID/NCEZID) < bez7@cdc.gov>

Subject: Florida Citrus Greening Situation

Hi,

I just wanted to let you know that on Friday, the crisis declaration went through. We added the following restrictions:

- PPE: Require enclosed cabs or "headgear" ensuring full coverage of the neck when enclosed cabs are not feasible.
- Refined commodity list to include the commodities listed in the 40 CFR 180.1 under the definition for fruit, citrus [Grapefruit, lemon, lime, orange, tangelo, tangerine, citrus citron, kumquat, and hybrids of these] plus pummelo.
  - \* Time-limited tolerances will be established for oxytetracycline at 0.4 ppm for all citrus commodities and for streptomycin at 2 ppm on citrus fruit and 6 ppm on dried citrus pulp.
- Pre-treatment soil sampling as a part of a monitoring program to be coordinated with the respective registrants (similar to the monitoring program conducted for streptomycin on grapefruit to control citrus canker under a Section 18).

We're also planning to do more in the future. I'll keep you posted as this issue moves forward and thank you very much for your input and willingness to help last week.

Susan.

Susan Jennings Public Health Liaison Office of Pesticide Programs (706) 355-8574 (office) (706) 355-8726 (fax) (703) 216-8627 (cell)

From: Jennings, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B3E06D481ADC45F296232CF2DE82A8B7-JENNINGS, SUSAN]

**Sent**: 2/5/2018 4:08:19 PM

**To**: Patel, Jean (CDC/OID/NCEZID) [vzp4@cdc.gov]

Subject: RE: CARB reporting follow-up: Strategic Planning System log in and other instructions

Ok. I'll make changes and send to you before forwarding to our people.

Thanks.

From: Patel, Jean (CDC/OID/NCEZID) [mailto:vzp4@cdc.gov]

**Sent:** Monday, February 05, 2018 10:24 AM **To:** Jennings, Susan < Jennings.Susan@epa.gov>

Subject: RE: CARB reporting follow-up: Strategic Planning System log in and other instructions

Susan

1. This is a CDC response. Please feel free to make changes. If you do, please send to us so that we have consistent messages.

2. [

### **Deliberative Process / Ex. 5**

Thanks for sending and let me know if you need more info.

Jean

From: Jennings, Susan [mailto:Jennings.Susan@epa.gov]

Sent: Monday, February 5, 2018 9:54 AM

To: Patel, Jean (CDC/OID/NCEZID) <vzp4@cdc.gov>

Subject: FW: CARB reporting follow-up: Strategic Planning System log in and other instructions

Importance: High

OCSPP: Section 2.4.3.1. CDC will work with FDA and EPA to evaluate the risk of environmental uses of antibiotics on human health.

## **Deliberative Process / Ex. 5**

Patricia Parrott
Senior Advisor/Homeland Security Lead
Field and External Affairs Division
Office of Pesticide Programs
US EPA (Mail Code 7506P)
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Phone: 703 305-0744 parrott.patricia@epa.gov

From: Jennings, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B3E06D481ADC45F296232CF2DE82A8B7-JENNINGS, SUSAN]

**Sent**: 2/5/2018 2:54:15 PM **To**: Jean Patel [vzp4@cdc.gov]

**Subject**: FW: CARB reporting follow-up: Strategic Planning System log in and other instructions

Attachments: CARB Strategic Planning System update template.xlsx; 2017.12.01 CARB NAP Output from Strategic Planning

System.xlsx

Importance: High

OCSPP: Section 2.4.3.1. CDC will work with FDA and EPA to evaluate the risk of environmental uses of antibiotics on human health.

## **Deliberative Process / Ex. 5**

Patricia Parrott
Senior Advisor/Homeland Security Lead
Field and External Affairs Division
Office of Pesticide Programs
US EPA (Mail Code 7506P)
1200 Pennsylvania Avenue, NW
Washington, DC 20460
Phone: 703 305-0744

parrott.patricia@epa.gov

From: Jennings, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B3E06D481ADC45F296232CF2DE82A8B7-JENNINGS, SUSAN]

**Sent**: 8/1/2017 12:56:51 PM

**To**: Jean Patel [vzp4@cdc.gov]; Heather.Harbottle@fda.hhs.gov

CC: Fajardo, Julius [Julius.Fajardo@ARS.USDA.GOV]; Garvie, Heather [Garvie.Heather@epa.gov]; Johnson, Hope

[Johnson.Hope@epa.gov]

Subject: FW: Federal interagency Antibiotic Resistance Call

Attachments: Streptomycin 152 Firewall 50WP 07032017\_JEF Comment.doc

Below are USDA's comments from Julius.

Thanks.

From: Fajardo, Julius [mailto:Julius.Fajardo@ARS.USDA.GOV]

Sent: Wednesday, July 26, 2017 3:34 PM

To: Jennings, Susan < Jennings.Susan@epa.gov>

Cc: Johnson, Hope < Johnson. Hope@epa.gov>; Sow, Fatima < Sow. Fatima@epa.gov>

Subject: RE: Federal interagency Antibiotic Resistance Call

Susan,

The process involved for these antibiotics is not a registration review, right?

Please find attached few comments of mine. My comments for streptomycin would be similar to the other two antibiotics.

Thanks and best regards,

Julius

From: Johnson, Hope [mailto:Johnson.Hope@epa.gov]

Sent: Thursday, July 20, 2017 3:09 PM

To: Sow, Fatima <<u>Sow.Fatima@epa.gov</u>>; Jennings, Susan <<u>Jennings.Susan@epa.gov</u>>; Kough, John

< Kough.John@epa.gov>; Collins, Samantha < collins.samantha@epa.gov>; Chandgoyal, Tara

< <u>Chandgoyal.Tara@epa.gov</u>>; Garvie, Heather < <u>Garvie.Heather@epa.gov</u>>; Giles-Parker, Cynthia < <u>Giles-</u>

Parker.Cynthia@epa.gov>; Schulze, Carl P - APHIS <Carl.P.Schulze@aphis.usda.gov>; Fajardo, Julius

<Julius.Fajardo@ARS.USDA.GOV>; Heather.Harbottle@fda.hhs.gov; Jean Patel <vzp4@cdc.gov>;

<u>Jeff.Gilbert@fda.hhs.gov</u>; Michael Craig <<u>bez7@cdc.gov</u>>; Hammond, Rose <<u>Rose.Hammond@ARS.USDA.GOV</u>>

Cc: Cook, Colwell < cook.colwell@epa.gov>; Britton, Cathryn < Britton.Cathryn@epa.gov>; Kaul, Monisha

<<u>Kaul.Monisha@epa.gov</u>>

Subject: RE: Federal interagency Antibiotic Resistance Call

Update: The draft Benefits reviews cannot be released at this time, however, they will be available to view during the public comment periods that are forthcoming.

Thank you, Hope

Hope A. Johnson
Product Manager 21
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division
Fungicide Branch

Phone: 703-305-5410 Mail Code 7505P

From: Johnson, Hope

Sent: Thursday, July 20, 2017 10:53 AM

To: Sow, Fatima <<u>Sow.Fatima@epa.gov</u>>; Jennings, Susan <<u>Jennings.Susan@epa.gov</u>>; Kough, John

<Kough.John@epa.gov>; Collins, Samantha <collins.samantha@epa.gov>; Chandgoyal, Tara

<Chandgoyal.Tara@epa.gov>; Garvie, Heather <Garvie.Heather@epa.gov>; Giles-Parker, Cynthia <Giles-</p>

Parker.Cynthia@epa.gov>; 'Carl Schultze' <Carl.P.Schulze@aphis.usda.gov>; Julius Fajardo

<Julius.Fajardo@ARS.USDA.GOV>; 'Heather.Harbottle@fda.hhs.gov' < Heather.Harbottle@fda.hhs.gov>; 'Jean Patel'

Hammond' < Rose. Hammond@ARS. USDA. GOV>

**Cc:** 'Cook, Colwell' <<u>cook.colwell@epa.gov</u>>; Britton, Cathryn <<u>Britton.Cathryn@epa.gov</u>>; Kaul, Monisha <<u>Kaul.Monisha@epa.gov</u>>

**Subject:** RE: Federal interagency Antibiotic Resistance Call

Thank you all again for your participation today on the call. Attached are all the Resistance Review documents for your review in one place. Our BEAD division is determining whether or not we can provide the draft Benefits documents as an FYI. The Benefits documents include discussion on efficacy and alternatives. We will forward those documents to you if we can as soon as possible.

We would appreciate any comments you have- please send as soon as possible and hopefully no later than COB Wednesday 7/26/2017.

Please send any comments to Susan Jennings and cc: myself (Hope Johnson) and Fatima Sow.

Again, please note that we are in the Risk Management stage of the review. In the coming few weeks, we will begin briefings for our Management along with drafting the Proposed Decision documents for each AI (active ingredient) in preparation for the Public Process. We hope to begin the Public Process by the beginning of October of this year. It will include a 30 day comment period and allows the public to look at all supporting documents associated with the Proposed Decision (Health Effects Division risk assessment, Environmental Fate and Effects Division risk assessment, Biological and Economic Analysis Division Benefits assessment, Resistance Review (former 152), proposed labels). The Proposed Decision will discuss any mitigation we are proposing for that specific AI's new use.

After the comment period has closed, the Agency responds to comments received and incorporates these responses along with any revisions to the Proposed Decision into a Final Decision document. This is then uploaded to the docket, the Registrations are signed, and the Final Rule is published establishing tolerances. We are striving to meet a January 2018 timeframe for the Final Decisions.

Please feel free to contact me if you have questions on the process.

Thank you,

Hope A. Johnson
Product Manager 21
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division
Fungicide Branch
Phone: 703-305-5410
Mail Code 7505P

From: Johnson, Hope

Sent: Thursday, July 20, 2017 8:18 AM

To: Sow, Fatima <Sow.Fatima@epa.gov>; Jennings, Susan <Jennings.Susan@epa.gov>; Kough, John

< Kough\_John@epa.gov>; Collins, Samantha < collins.samantha@epa.gov>; Chandgoyal, Tara

<a href="mailto:chandgoyal.Tara@epa.gov">chandgoyal.Tara@epa.gov</a>; Garvie, Heather <a href="mailto:Garvie.Heather@epa.gov">Garvie, Heather@epa.gov</a>; Giles-Parker, Cynthia <a href="mailto:Giles-Parker">Garvie.Heather@epa.gov</a>; Giles-Parker</a>; Giles-Parker</a>; Giles-Parker</a>; Giles-Parker</a>; Giles-Parker</a>; Giles-Parker</a>; Giles-Parker</a>; Giles

Parker.Cynthia@epa.gov>; Carl Schultze < Carl.P.Schulze@aphis.usda.gov>; Julius Fajardo

<Julius.Fajardo@ARS.USDA.GOV>; Heather.Harbottle@fda.hhs.gov; Jean Patel <vzp4@cdc.gov>;

Jeff.Gilbert@fda.hhs.gov; Michael Craig <bez7@cdc.gov>; Rose Hammond <Rose.Hammond@ARS.USDA.GOV>

Cc: Cook, Colwell <a href="mailto:cook.colwell@epa.gov">cook.colwell@epa.gov</a>>; Britton, Cathryn <a href="mailto:cook.colwell@epa.gov">Britton, Cathryn@epa.gov</a>>

Subject: RE: Federal interagency Antibiotic Resistance Call

The original streptomycin grapefruit/tomato 152 review is attached here. Previously only the addendum was attached. This is the complete document.

Hope A. Johnson
Product Manager 21
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division
Fungicide Branch
Phone: 703-305-5410

From: Sow, Fatima

Mail Code 7505P

Sent: Wednesday, July 19, 2017 4:49 PM

Documents to be discussed are attached.

----Original Appointment----

From: Jennings, Susan

Sent: Monday, June 19, 2017 10:19 AM

**To:** Jennings, Susan; Kough, John; Collins, Samantha; Chandgoyal, Tara; Garvie, Heather; Johnson, Hope; Giles-Parker, Cynthia; Carl Schultze; Julius Fajardo; <a href="mailto:Heather:Harbottle@fda.hhs.gov">Heather:Harbottle@fda.hhs.gov</a>; Jean Patel; <a href="mailto:Jeff.Gilbert@fda.hhs.gov">Jeff.Gilbert@fda.hhs.gov</a>; Michael

Craig; Rose Hammond

Cc: Sow, Fatima

Subject: Federal interagency Antibiotic Resistance Call

When: Thursday, July 20, 2017 8:00 AM-10:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: Conference call # 866-299-3188, code 7063558524

Documents to be discussed are attached to this invitation.

This is just a hold until we find a time that works for Federal Partners. Final meeting will be scheduled for 2 hours (but may be shorter).

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#### Message

From: Jennings, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B3E06D481ADC45F296232CF2DE82A8B7-JENNINGS, SUSAN]

**Sent**: 3/20/2018 2:48:24 PM

To: Fajardo, Julius [Julius.Fajardo@ARS.USDA.GOV]; Patel, Jean (CDC/OID/NCEZID) [vzp4@cdc.gov]; Schulze, Carl P -

APHIS [Carl.P.Schulze@aphis.usda.gov]; Harbottle, Heather (FDA/CVM) [Heather.Harbottle@fda.hhs.gov]; Gilbert, Jeffrey M (FDA/CVM) [Jeff.Gilbert@fda.hhs.gov]; Craig, Michael R. (CDC/OID/NCEZID) [bez7@cdc.gov]; Hammond,

Rose [Rose.Hammond@ARS.USDA.GOV]

Subject: RE: Meeting?

Great, how about 9-12 (or so, maybe we can do it in 2 hours), on the 10<sup>th</sup>?

It seems that we can have at least one rep from each of the agencies.

From: Fajardo, Julius [mailto:Julius.Fajardo@ARS.USDA.GOV]

Sent: Monday, March 19, 2018 12:50 PM

**To:** Jennings, Susan <Jennings.Susan@epa.gov>; Patel, Jean (CDC/OID/NCEZID) <vzp4@cdc.gov>; Schulze, Carl P - APHIS <Carl.P.Schulze@aphis.usda.gov>; Harbottle, Heather (FDA/CVM) <Heather.Harbottle@fda.hhs.gov>; Gilbert, Jeffrey M (FDA/CVM) <Jeff.Gilbert@fda.hhs.gov>; Craig, Michael R. (CDC/OID/NCEZID) <bez7@cdc.gov>; Hammond, Rose <Rose.Hammond@ARS.USDA.GOV>

Subject: RE: Meeting?

Free on the 9th and the 10th (AM only). Thanks.

From: Jennings, Susan [mailto:Jennings.Susan@epa.gov]

**Sent:** Monday, March 19, 2018 12:16 PM

**To:** Patel, Jean (CDC/OID/NCEZID) <<u>vzp4@cdc.gov</u>>; Schulze, Carl P - APHIS <<u>Carl.P.Schulze@aphis.usda.gov</u>>; Fajardo, Julius <<u>Julius.Fajardo@ARS.USDA.GOV</u>>; Harbottle, Heather (FDA/CVM) <<u>Heather.Harbottle@fda.hhs.gov</u>>; Gilbert, Jeffrey M (FDA/CVM) <<u>Jeff.Gilbert@fda.hhs.gov</u>>; Craig, Michael R. (CDC/OID/NCEZID) <<u>bez7@cdc.gov</u>>; Hammond, Rose <Rose.Hammond@ARS.USDA.GOV>

Subject: RE: Meeting?

Perfect!! Glad to hear it.

Others??

From: Patel, Jean (CDC/OID/NCEZID) [mailto:vzp4@cdc.gov]

Sent: Monday, March 19, 2018 12:15 PM

To: Jennings, Susan <<u>Jennings.Susan@epa.gov</u>>; Carl Schultze <<u>Carl.P.Schulze@aphis.usda.gov</u>>; Julius Fajardo <<u>Julius.Fajardo@ARS.USDA.GOV</u>>; Harbottle, Heather (FDA/CVM) <<u>Heather.Harbottle@fda.hhs.gov</u>>; Gilbert, Jeffrey M (FDA/CVM) <<u>Jeff.Gilbert@fda.hhs.gov</u>>; Craig, Michael R. (CDC/OID/NCEZID) <<u>bez7@cdc.gov</u>>; Rose Hammond <<u>Rose.Hammond@ARS.USDA.GOV</u>>

Subject: RE: Meeting?

Susan – I will be in DC on the 8th and 9th for a meeting. The 10th might be best for me and I would stay an extra day.

From: Jennings, Susan [mailto:Jennings.Susan@epa.gov]

Sent: Monday, March 19, 2018 11:55 AM

To: Carl Schultze <Carl.P.Schulze@aphis.usda.gov>; Julius Fajardo <Julius.Fajardo@ARS.USDA.GOV>; Harbottle, Heather (FDA/CVM) <Heather.Harbottle@fda.hhs.gov>; Patel, Jean (CDC/OID/NCEZID) <vzp4@cdc.gov>; Gilbert, Jeffrey M (FDA/CVM) <Jeff.Gilbert@fda.hhs.gov>; Craig, Michael R. (CDC/OID/NCEZID) <bez7@cdc.gov>; Rose Hammond

<Rose.Hammond@ARS.USDA.GOV>

Subject: Meeting?

Hi all,

We are about to start working on the registration review of streptomycin and oxytetracycline. As you may recall from our earlier meeting, this process is a review of existing labels and uses. Some uses that we've discussed include homeowner uses and application by air.

I will be travelling to DC the week of May 7<sup>th</sup> and was hoping that we might be able to have a face-to-face meeting on the 9<sup>th</sup> or 10<sup>th</sup>, at least for those of you who are in town? Maybe a half-day or a bit longer? We haven't met for a while and it would be a good chance to regroup and rethink our approach to these compounds, especially in light of what we have learned from the recent new uses.

Please let me know if you think you will be available.

Thanks,

Susan.

Susan Jennings Senior Advisor for Public Health Office of Pesticide Programs (706) 355-8574 (office) (703) 216-8627 (cell)

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#### Message

From: Suarez, Mark [Suarez.Mark@epa.gov]

**Sent**: 8/24/2018 12:34:46 PM

To: Jennings, Susan [Jennings.Susan@epa.gov]

Subject: RE: Draft of Environmental AMR Report - Time Sensitive Response by 8/23

Attachments: Triazole and DeMethylation and Other Fungicides-FINAL SIGNED.PDF

Susan,

I made a number of comments. I could make more, if I had more time. If there is more time or another opportunity to comment, please let me know. I'm also attaching the March 2018 triazole/DMI memo that I referenced in my comments for convenience.

Regards,

Mark

Mark Suarez
Entomologist
Science Information and Analysis Branch
Biological and Economic Analysis Division
US EPA (Mail Code 7503P)
1200 Pennsylvania Avenue, NW
Washington, DC 20460

phone: 703-305-0120

From: Jennings, Susan

**Sent:** Thursday, August 23, 2018 1:46 PM **To:** Suarez, Mark <Suarez.Mark@epa.gov>

Subject: RE: Draft of Environmental AMR Report - Time Sensitive Response by 8/23

Here you go.

Thx.

From: Suarez, Mark

**Sent:** Thursday, August 23, 2018 1:28 PM **To:** Jennings, Susan < <u>Jennings, Susan@epa.gov</u>>

Subject: RE: Draft of Environmental AMR Report - Time Sensitive Response by 8/23

Susan,

Wynne asked that I provide comments. I don't seem to be able to access the shared version on OneDive. Would you mind sending the link to me?

Regards, Mark

Mark Suarez Entomologist

Science Information and Analysis Branch Biological and Economic Analysis Division US EPA (Mail Code 7503P) 1200 Pennsylvania Avenue, NW

Washington, DC 20460

phone: 703-305-0120

From: Miller, Wynne

Sent: Thursday, August 23, 2018 10:10 AM

To: Chandgoyal, Tara < <a href="mailto:Chandgoyal.Tara@epa.gov">Cook, Colwell < <a href="mailto:cook.colwell@epa.gov">Cook, Colwell@epa.gov</a>; Kaul, Monisha

<Kaul.Monisha@epa.gov>

Cc: Jones, Arnet < <u>Jones.Arnet@epa.gov</u>>; Suarez, Mark < <u>Suarez.Mark@epa.gov</u>>
Subject: RE: Draft of Environmental AMR Report - Time Sensitive Response by 8/23

I have one minor edit before you give to Susan on page 50. I'm also cc'ing Suarez in case he has anything regarding the triazole stuff.

From: Chandgoyal, Tara

Sent: Wednesday, August 22, 2018 2:37 PM

To: Cook, Colwell < cook.colwell@epa.gov >; Kaul, Monisha < Kaul.Monisha@epa.gov > Cc: Jones, Arnet < Jones.Arnet@epa.gov >; Miller, Wynne < Miller.Wynne@epa.gov > Subject: RE: Draft of Environmental AMR Report - Time Sensitive Response by 8/23

Hello Colwell and Monisha:

As per Colwell's direction I reviewed the subject document sent by Susan Jennings.

My minor editorial comments are marked in the document on the link sent by Susan Jennings.

A copy of the document is attached (in case you need it in the future).

Thanks.

Tara Chanddgoyal

From: Jennings, Susan

Sent: Wednesday, August 15, 2018 1:36 PM

To: Johnson, Hope < Johnson. Hope@epa.gov>; Giles-Parker, Cynthia < Giles-Parker. Cynthia@epa.gov>; Sow, Fatima

<<u>Sow.Fatima@epa.gov</u>>; Garvie, Heather <<u>Garvie.Heather@epa.gov</u>>; Manupella, Matthew

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Cook, Colwell <cook.colwell@epa.gov>; Chandgoyal, Tara <Chandgoyal.Tara@epa.gov>; Kough, John

< Kough\_John@epa.gov>; Collins, Samantha < collins.samantha@epa.gov>; Dawson, Jeffrey < Dawson.Jeff@epa.gov>;

Swartz, Christina < Swartz. Christina@epa.gov>

**Cc:** Goodis, Michael < Goodis Michael@epa.gov>; Rosenblatt, Daniel < Rosenblatt.Dan@epa.gov>; Davis, Donna < Davis.Donna@epa.gov>; Guilaran, Yu-Ting < Guilaran.Yu-Ting@epa.gov>; Smith, Charles < Smith.Charles@epa.gov>

**Subject:** Draft of Environmental AMR Report - Time Sensitive Response by 8/23

Hello all,

CDC is a lead author on the attached document and will either host or link to the document in early-mid September. The report came out of the International Environmental Antimicrobial Resistance Forum held in Vancouver this Spring. It discusses the various potential pathways for antibiotic-resistance to develop in the environment that may ultimately affect human health.

This document addresses not only the use of antibiotic drug use on plants, but also the potential for **indirect resistance coming from the use of the triazoles and coppers**. Because expertise on these compounds is spread across OPP, please feel free to forward this as appropriate (but, please allow adequate time to review).

CDC has requested a scientific accuracy review (not language or writing, since they are still working on those) for the attached document. They originally asked for a response by this Friday, but were willing to extend it to **next Thursday** (the 23rd).

The pesticides discussion is contained on pages 50-84. The attached document is a link to OneDrive. If all reviewers could *please* use the full word and track changes we can be sure the comments are conveyed to CDC.

Thanks for your help and please let me know if you have any questions or comments,

Susan.

Susan Jennings Senior Advisor for Public Health Office of Pesticide Programs (706) 355-8574 (office) (703) 216-8627 (cell)

### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON D.C., 20460

Morrona (aul



MAR 0 9 2018

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Juhad A Hleaded Feb-27, 2018

Tora Wondgesper !

## **MEMORANDUM**

SUBJECT: Uses and Usage of Triazole and DeMethylation Inhibitor (DMI) Fungicide

**Pesticides** 

FROM: Mark Suarez, Entomologist

Jihad Alsadek, Economist

Scientific Information and Analysis Branch,

Biological and Economic Analysis Division (7503P)

Tara Chandgoyal, Plant Pathologist

Biological Analysis Branch,

Biological and Economic Analysis Division (7503P)

THRU:

Monisha Kaul, Chief

Biological Analysis Branch

Diann Sims, Chief Aller Scientific Information and Analysis Branch,

Biological and Economic Analysis Division (7503P)

TO:

Cynthia Giles-Parker, Chief

Fungicide Branch

Registration Division (7505P)

Susan Jennings

Director's Office

Office of Pesticide Programs (7501P)

Product Review Panel: September 27, 2017

Aspergillus fumigatus, is a ubiquitous saprophytic fungus found in both soil and air. This fungus is a facultative human pathogen, which is treated with clinical triazoles. Resistance to clinical triazoles has long been documented in A. fumigatus (Denning et al 1997). Some authors have hypothesized that this may be the result of non-clinical triazole usage (e.g., Kano et al 2014, Ribas et al 2016). Specifically, authors have postulated that agricultural and floricultural use of triazole pesticides could be responsible for the presence of triazole resistant A. fumigatus in the environment (e.g., Berger et al 2017). The Centers for Disease Control and Prevention (CDC) requested that OPP provide information related to triazole use and usage. The information contained herein is intended to summarize available data about pesticide uses and usage in the United States (US). These data are not adequate to link triazole resistance in A. fumigatus to any pesticidal use or uses; rather, the information is intended to better inform epidemiological investigations into the origins of clinical triazole resistance in A. fumigatus.

Triazole fungicides have been registered for use as pesticides in the US since 1952. Fourteen triazole fungicides (cyproconazole, difenoconazole, fenbuconazole, flutriafol, ipconazole, metconazole, myclobutanil, propiconazole, prothioconazole, tebuconazole, tetraconazole, triadimefon, triadimenol, and triticonazole) are currently registered pesticides in the US. These are broad spectrum fungicides effective against a wide variety of plant fungal pests. In the US, the triazole fungicides are registered for use in sites that range from agricultural crops to industrial applications to consumer products labeled for use in and around residential areas (see Table 1).

Resistance to triazoles and related compounds has been reported in the public literature for various phytopathogenic fungal species (Cools *et al* 2013). The Fungicide Resistance Action Committee (FRAC) classifies all triazole pesticides, as well as some other chemical groups, as demethylation inhibitors (DMI) fungicides, FRAC Group 3 (FRAC 2017). The DMI fungicides inhibit sterol biosynthesis in target fungi. Several resistance mechanisms have been identified across fungal species (FRAC 2017). While the level of cross-resistance between DMI fungicides is undetermined, FRAC recommends treating individual phytopathogens exhibiting resistance as cross-resistant to the group (FRAC 2017). For this reason, information is presented herein on all DMI fungicides registered in the US, rather than the triazoles alone. The additional active ingredients included in this analysis are: triforine, imazalil, and triflumizole.

Registered use site and usage information are likely useful for the purpose of understanding where the highest potential for evolution (and/or maintenance) of resistance is likely to occur and the relative importance of individual DMI fungicide active ingredients with respect to focusing epidemiological investigations. Table 1 shows the US-registered DMI fungicides and generalized use sites associated with each active ingredient (AI). It is important to note that the use sites listed are not exhaustive, but are indicative of the type and range of uses registered for each AI. The uses associated with the highest usage, in terms of the number of pounds of DMI active ingredient applied, are highlighted (wheat, corn, peanut, soybean, and rice). Table 2 provides the average annual DMI usage by active ingredient for the three most recent years of survey data (2013-2015). Propiconazole and tebuconazole are the most widely and heavily used chemicals listed.

The agricultural usage data available (AMRD 2015), indicate that between 1998 and 2006 total DMI usage across all reported crops was relatively stable at approximately 1 million pounds of active ingredient (lb AI) per year. Reported DMI usage in the US began to increase steadily in the mid-2000s. This is likely, at least in part, in response to the reemergence of Fusarium blight in the 1990's

(McMullen et al. 2012). Between 2011 and 2015, DMI fungicide usage on surveyed crops increased from approximately 3 million lb AI to approximately 5 million lb AI. This rise was largely attributable to increased usage, in terms of total lb AI applied, in the top 5 crops over this period: wheat, peanuts, corn, soybean, and rice. Triazole usage on wheat was more than double the usage (both lb AI and acreage) on peanuts, the crop with the second highest usage. During 2011-2015 wheat accounted for more than 40% of the triazoles (lb AI) used on agricultural crops. Peanuts and corn accounted for nearly another 30% during that period. These three crops, combined with soybeans, rice, sugar beets, almonds, wine grapes, and apples account for more than 90% of triazole usage on surveyed crops between 2011 and 2015. The data from 2013-2015 (Table 4) suggest relatively modest changes in the usage of triazoles and other DMI fungicides relative to the 2011-2015 usage averages. The total pounds of DMIs used on corn was second to wheat, peanuts usage moved to third. Soybean and rice still rounded out the top five crops in terms of pounds of DMIs applied for the most recent three years of available data.

In terms of acres treated (Table 4), the top two crops were again wheat and corn from 2013-2015. Soybean, cotton, peanuts, rice, and almonds are also high acreage crops, each averaging over a million acres treated annually. Because soybean and cotton are high acreage crops, use of the Als on only on a small percentage of the acreage grown can still lead to high total usage. In terms of the percent crop treated (PCT), the top crops are very different. Celery (60%), artichoke (60%), garlic (45%), and grapefruit (40%) have the highest PCTs with numerous crops around 30% PCT (rice, table grapes, peanuts, hazelnuts, caneberries, cranberries, and tomatoes) (Tables 3a & 4). The top crop in terms of pounds Al applied per year and total acreage grown, wheat, averages barely 10% of the crop treated. Corn and soybeans PCTs are in the low single digits.

USDA's National Agricultural Statistics Service (NASS) provides limited, and somewhat dated data, on DMI fungicide usage in the non-agricultural sector for floriculture and nursery operations from the years 2006 and 2009 (NASS 2016). Nevertheless, those data are useful for understanding the potential for DMI exposure in this sector. Those data are presented in terms of the percentage of operation reporting usage, rather than percent crop treated (Table 3b). In those market spaces, the survey data showed that in 2006 and 2009, DMI usage was reported for 15 and 18% of cut flower and cut cultivated green operations, respectively. The reported use of DMI fungicides in terms of pounds of active ingredient applied is markedly higher in floriculture than nurseries, but both are relatively minor usages in terms of total pounds of DMI fungicides applied when compared to agricultural crops.

Although also limited and dated, consumer pesticide usage data suggest that there is the potential for exposure from residential and recreational use site applications of DMI fungicides (NMRD 2012). These exposures can be through pesticides applied by consumers or professional applicators. The use site information captured by the Agency does not clearly identify consumer products. Only triforine was clearly associated with consumer products, although professional applicators may use them. The proprietary consumer pesticide usage information available provides information adequate to calculate that the total annual consumption of DMI fungicide AIs by consumers totaled between 360,000 and 500,000 pounds. Furthermore, the estimated total professional annual usage on turf and ornamentals (T&O) equaled nearly 400,000 pounds of DMI fungicide AIs. The vast majority of this T&O usage was on golf courses. Together, annual DMI fungicide usage in areas where people live, work, and play was estimated to be as much as 900,000 pounds.

In addition to the presence of DMI fungicides in outdoor spaces, there is a theoretical potential for *A. fumigatus* exposure pesticide residues on food commodities (and in water). While aggregate exposure estimates to DMIs are not readily available, the Agency's re-evaluation of propiconazole (EPA 2006) included a conservative estimation of the acute aggregate triazole exposures. Total dietary exposure from food and drinking water, even at the 95th percentile of exposure, is anticipated to be low for triazoles. This is consistent with USDA Pesticide Data Program (PDP 2015) results, which indicate very low DMI fungicide residues. The number of detectable residues across all sampled commodities from 2011-2015 was 1.5% on average. The maximum average across that time for any single commodity was less than 5%. Thus, the actual potential for the evolution and/or maintenance of resistance of *A. fumigatus* as a result of exposure to food or water supplied appears to be unlikely.

#### References:

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PDP. 2015. United Stated Department of Agriculture. Pesticide Data Program. (2015). Retrieved October 17, 2017 from https://www.ams.usda.gov/datasets/pdp

US EPA OPPIN Query, 2017. United States Environmental Protection Agency. Office of Pesticide Programs. Retrieved October, 2017 from Office of Pesticide Programs Information Network.

Table 1. US registered use sites for triazole and other DMI pesticide active ingredients.

|   |                  |                 |   |                |  |     | Triazoles    |          |  |         |          |     |             |          |        |   |       | Other DMI<br>Fungicides |    |  |
|---|------------------|-----------------|---|----------------|--|-----|--------------|----------|--|---------|----------|-----|-------------|----------|--------|---|-------|-------------------------|----|--|
| USE SITE  | ACTIVE<br>INGRES | Sperior Control | de de la companya de |                | 6833<br>38 38<br>38 38 38<br>38 38 38<br>38 38 38<br>38 38 38<br>38 38 38<br>38 38 38 38<br>38 38 38 38<br>38 38 38 38 38<br>38 38 38 38 38 38 38 38 38 38 38 38 38 3 |     |              |          |  |         |          |     |             |          |        |   |       |                         |    |  |
| AGRICULTURAL CROPS  |                  | Ţ               | T   | lacksquare     |  |     |              |          |  |         |          |     |             |          |        |   |       |                         | ,  |  |
| RUITS   |                  | +-              | +   |                | <u> </u>   |     | _            |          | _  |         |          |     |             |          |        |   | <br>  |                         | 1  |  |
| CITIES CONDITION - avenue lavery lines area fault at 3  |                  | 1.              | ١.,   |                |  |     |              | v        |  |         |          |     |             |          |        |   | 32    |                         |    |  |
| CITRUS FRUITS (e.g., orange, lemon, lime, grapefruit, etc) POME FRUITS (e.g., apple, pear, quince, etc) |                  | O<br>X          |   |                | -  |     | 0            | X<br>O   | Х  | _       |          |     | _           |          |        |   | <br>Х | ×                       | i  |  |
| STONE FRUITS (e.g., appic) pear, quinte, etc)   |                  | <del> </del> ↑  |   |                | -  | Х   | 0            | X        | X  | -       |          |     | -           |          |        |   | <br>  | 0                       |    |  |
| SMALL FRUITS (berries, currant, grape, kiwi, etc)   |                  | +-              | +^  | <del>†</del> ^ | $\vdash$   | ~   | <u> </u>     | ^        | <u>  ^</u>                                       | -       | $\vdash$ |     | -           |          | X      | - | <br>  |                         |    |  |
| Canaberries (e.g., blackberries and raaspberries)   |                  | +               | +-  | †              | ╁  |     | 0            | Х        | <del> </del>                                     |         |          |     | -           | -        | ~      |   | <br>  |                         |    |  |
| Bushberries (e.g., blueberries and currents)  |                  | +               | 0   | 0              | $\vdash$   | Х   | 0            | Х        | $\vdash$   |         |          |     |             |          | 0      |   | <br>  |                         |    |  |
|   |                  | +               | Ť   | Ť              | $\vdash$   |     | <del>-</del> | <u> </u> | ┢  | -       |          |     |             |          | _      |   | <br>  |                         |    |  |
| Small climbing fruit vines (e.g. grapes and gooseberries)   |                  | 0               |   | 0              |  |     | 0            |          |  | χ       |          |     |             |          |        |   |       | Х                       |    |  |
| Low growing berries (e.g., cranberry and strawberry)  | $\neg \vdash$    | X               |   |                | T  |     | Ö            | Х        | $\vdash$   | х       |          |     |             | $\vdash$ | _      |   | <br>  | 0                       | 1  |  |
| SUBTROPICAL/TROPICAL FRUITS (e.g., banana, mango,   |                  | +               | 1   | T              | T  |     |              |          | $\vdash$   |         |          |     |             | $\vdash$ | _      |   | <br>  | М                       | 1  |  |
| sineappie, etc)   |                  | -               | 0   |                |  |     | Х            | 0        | Х  |         | 0        |     |             |          |        |   |       | 0                       |    |  |
| NUTS & SEEDS  |                  |                 | I   | I              | $\Box$   |     |              |          |  |         |          |     |             |          |        |   |       |                         | ı  |  |
| TREE NUTS (e.g., almond, pecan, walnut, etc)  |                  | χ               | 0   | X              |  | Х   | 0            | Х        | Χ  | ۵       |          |     |             |          |        |   |       | 0                       |    |  |
| OIL SEEDS (e.g., canola, crambe, sunflower, etc)  |                  | 0               |   |                | 0  | 0   |              | Х        | O  |         |          |     |             |          | O      |   |       |                         |    |  |
| GRAINS  |                  | Т_              | $\perp$   | $oxed{\Box}$   | <u> </u>   |     |              |          |  |         |          |     |             |          |        |   |       |                         |    |  |
| CEREAL GRAINS   | E                | 3 0             | 0   | 0              | Х  | 0   |              | Х        | Ü  | Ð       |          | 0   | 0           |          | Х      |   |       |                         |    |  |
| BARLEY  |                  | X               |   | <u> </u>       | Х  | Х   |              | Х        | Х  |         |          | X   | Х           |          | Х      |   | χ     |                         | ,  |  |
| BUCKWHEAT   |                  |                 |   | <u> </u>       | Х  |     |              | Ü        |  |         |          |     |             |          | Х      |   |       |                         | ,  |  |
| CORN  | 2                | ( 0             | 4   | ×              | ×  | Х   |              | X        | Х  | ×       |          | X   | Х           |          | Х      |   |       |                         | ,  |  |
| MILLET  |                  | ┷               | 1   | ↓              | X  |     |              | Ü        |  |         |          |     |             |          | Х      |   | <br>  |                         | ,  |  |
| OATS  |                  | l X             | ــــ  |                | X  | Х   |              | Х        | Х  |         |          | X   | Х           |          | Х      |   | <br>  |                         | ,  |  |
| RICE  |                  | 4.              | 4   | -              | ×  |     |              | ×        |  |         |          |     |             |          | ×      |   |       |                         | 1  |  |
| RYE   |                  | X               | +   | +-             | X  | Х   |              | X        | X  |         |          | X   | X           |          | X      |   | <br>  |                         | í  |  |
| SORGHUM<br>TRITICALE  | -                | < x             | +   | X              | X  | Х   |              | ×        | X  | -       |          |     | X           |          | 0<br>X |   | <br>χ |                         |    |  |
| WHEAT   | 3                |                 |   | <del></del>    | Ê  | ×   |              | ×        | ŵ  |         |          | X   | ×           |          | ×      |   | ×     |                         |    |  |
| VEGETABLES  |                  |                 | 7   | ***            | -  |     |              |          |  |         | *******  |     |             |          |        |   | <br>  |                         |    |  |
| ROOT AND TUBER VEGETABLES (e.g., beets, carrots, potato,  | _                | +               | +   | +-             | ╁  |     |              | -        | -  | -       |          |     | -           |          | _      |   | <br>  |                         |    |  |
| radish, sweet potato, etc)  |                  | 0               | 0   | 0              | X  | 0   | 0            | 0        | 0  | o       |          |     |             |          | 0      |   |       |                         |    |  |
| BULB VEGETABLES   |                  | $\top$          | T   | T              | T  |     |              | Х        | Х  |         |          |     |             |          |        |   | <br>  |                         |    |  |
| Bulbs (e.g., gariic, onion, shallot)  |                  | 0               | $^{\dagger}$  | Х              | T  |     |              | Х        | 0  |         |          |     |             |          |        |   |       |                         | I  |  |
| Greens (e.g., leeks, green onions, etc)   |                  | 0               | T   |                |  |     |              | Х        | 0  |         |          |     |             |          |        |   |       |                         | 1  |  |
| LEAFY VEGETABLES  |                  | T               | T   | Х              | Χ  |     | 0            | 0        | 0  |         |          |     |             |          | 0      |   |       | 0                       | 1  |  |
| VEGETABLE STEMS [leafy petioles] (e.g., celery; rhubarb; Swiss  |                  | Т               | T   |                |  |     |              |          |  |         |          |     |             |          |        |   |       |                         | 1  |  |
| chard, etc)   |                  | $\perp$         |   | X              |  |     |              | Х        |  |         |          |     |             |          |        |   |       | Х                       |    |  |
| COLE CROPS (e.g., broccoli, cabbage, cauliflower, collards,   |                  |                 |   |                |  |     |              |          |  |         |          |     |             |          |        |   |       |                         |    |  |
| kale, etc)  |                  | X               | 1   | X              | Χ  |     |              |          | O  |         |          |     |             |          |        |   | <br>  | Х                       |    |  |
| FRUITING VEGETABLES (e.g., eggplant, okra, pepper, tomato,  |                  |                 |   |                |  |     |              |          |  |         |          |     |             |          |        |   |       |                         |    |  |
| etc)  |                  | 6               | 0   | Х              | <u> </u>   |     | O            | Ω        | Х  | L_      |          |     | Щ           |          |        |   | <br>  | 0                       | ,  |  |
| CUCURBIT VEGETABLES (e.g., cucumber, gourds, melons,  |                  |                 |   |                |  |     |              |          |  |         |          |     |             |          |        |   |       |                         |    |  |
| pumpkin, squash, etc)   |                  | X               | +   | X              | Х  |     | Χ            | $\vdash$ | X  | _       |          |     | <u> </u>    |          | X      |   | <br>  | Х                       | i  |  |
| LEGUMES (e.g., beans, chickpeas, lentils, peas, soybeans,   | .   .            | ,   _           | _   |                |  |     | _            | ا ٍ ا    | ا ا  |         |          |     |             |          | إ      |   |       |                         |    |  |
| etc)<br>BEANS   | <del>-   c</del> | 3 0             | 0   | 0              |  | ۵   |              |          | 0  | IJ      |          |     | -           | -        | 0      |   | <br>  | -                       |    |  |
| GARBANZOS (INCLUDING CHICK PEAS)  |                  |                 | +   | +              | 0  |     | 0            | 0        | Х  |         |          |     | -           | -        | X      |   | <br>  |                         |    |  |
| GARBANZUS (INCLUDING CHICK PEAS) PEANUTS  |                  | X               | 1×  | ×              | ×  | ж   |              | Х        | Х  | ×       |          |     |             |          | ×      |   |       |                         |    |  |
| PEAS & LENTILS  |                  | 4               | <del>1</del> *  | 1 ***          | 0  | •   |              |          | **   | -50     |          |     |             |          | X      |   |       |                         |    |  |
| SOYBEANS  |                  | ( x             | +   | ×              | <del></del>  | Х   | ×            | ×        | х  | ×       |          |     |             |          | ×      |   |       |                         |    |  |
| UNGROUPED   |                  | 7               | #   | †**            | 1  |     |              |          | -  | <u></u> |          |     |             |          |        |   |       |                         |    |  |
| ALFALFA   |                  | +               | +   | +              | $\vdash$   |     |              | $\vdash$ | -  |         |          |     | $\vdash$    | $\vdash$ | Х      |   | <br>  | $\vdash$                |    |  |
| BLUEGRASS   |                  | +               | +   | t              | $\vdash$   |     | Х            | $\vdash$ | <del>                                     </del> |         | $\vdash$ |     | $\vdash$    | $\vdash$ |        | - | <br>  | Н                       |    |  |
| HQPS  |                  | +               | +   | t              | $\vdash$   |     | X            |          | Х  | _       |          |     | <del></del> |          |        |   | <br>  | ×                       |    |  |
|   |                  | -+              | +   | +              | +  |     |              |          |  | -       | -        |     | <del></del> |          | -      | - | <br>  |                         |    |  |
|   | - 1              | l X             | 1   | I X            | l X  | , X | X            |          | 1 X I  |         | ,        | - х |             |          |        |   |       |                         |    |  |
| COTTON (UNSPECIFIED) MINT/PEPPERMINT/SPEARMINT  |                  | X               | ╁   | X              | ×  | Х   | X            | Х        | Х  |         |          | X   | -           |          |        |   | <br>  |                         | ļ. |  |

Table 1 (continued). US registered uses for triazole and other DMI pesticide active ingredients.

|   |                 |  |         |  | /  | 7  | $\overline{}$ | $\overline{}$  | 7  | 7  | 7                  | $\overline{Z}$  | 7                             | 7             | 7        | $\overline{}$ | $\overline{}$ | $\overline{}$ | 7  |               |
|---|-----------------|--|---------|--|--|--|---------------|----------------|--|--|--------------------|-----------------|-------------------------------|---------------|----------|---------------|---------------|---------------|--|---------------|
|   | ACTIVE<br>INCRE | 4  |         | al (1)   | 89   |  |               | × /            | 2/3/3/<br>2/3/3/<br>2/3/3/3/3/3/3/3/3/3/3/3/3/   | N.   | 6X)                |                 | 9)                            |               |          | 5/            | ٠ð٧           | //            |  |               |
|   | - Glar          | JEN<br>JEN   | کھر     | V)   | %<br>}   | <b>%</b>   | 2000          | 26             | 7,3  | %))  | Z)                 | Ø.              |                               |               | ŝ        | Z3)           | 7             | Š             | /s)  |               |
|   | PO RE           | 3.6  | 9/      | 20 20 20 E   |  | X  | 9/\           | y <sub>8</sub> | Ž  | ×29  | %\\                |                 |                               | ×3>           | 8        | Υ,            | 12            | %             | X  | <i>",",</i> " |
|   | MC.             | <b>%</b> /   | , cor   | 20 S   | 9/2  | 9%   | 69°, c        | 97.3           | 9.0  | 95%  | 39 <sup>7</sup> .6 |                 |                               | £),69         | ¥.       | /39           | 9%            | 3 × 8         | 59 X   | all ridge     |
| USE SITE  | • /             |  | 039     |  |  | Ð,   | SE,           | 22/2           |  | 39%,   | <i>i</i> %,        | 30%             | 3 <sup>6</sup> / <sub>2</sub> | <b>*</b>      | /4       | <i>.</i>      | Ż,            | 3)X           |  |               |
| AGRICULTURAL PRODUCTION SITES                         |                 | Ť  | Ť       | 7  | Ť  | Ť  | Ť             | Ť              | Ť  | ŕ  |                    |                 |                               | ŕ             | 一        | -1            |               | <b>ŕ</b>      | Ť  | ĺ             |
| POULTRY HATCHERY PREMISES AND EQUIPMENT               |                 | ┪  | ╈       | _  | ╅  | ╅  | T             | ⇈              | T  | ╅  |                    | _               | $\neg$                        | 一十            | ヿ        |               |               | Х             | T  | ĺ             |
| MUSHROOM HOUSES-EMPTY PREMISES/EQUIPMENT              |                 | 1  | T       | 1  | Г  | m  | T             | Х              | T  | m  |                    | $\neg$          | 一                             | 7             | $\neg$   |               |               | l             | T  | ĺ             |
| ORNAMENTAL/TURF                                       |                 |  |         |  |  |  |               |                |  |  |                    |                 |                               |               |          |               |               |               |  |               |
| COMMERCIAL/INDUSTRIAL LAWNS                           |                 | -  | +       | _  | ╁  | ┢  | <del> </del>  | Х              | <del>                                     </del> | <del> </del>                                     | Х                  | $\neg \uparrow$ | Х                             | $\dashv$      | $\neg$   |               |               | _             | _  | İ             |
| FLOWERS   |                 | 10   | +       | +  | <del>                                     </del> | ┢  | 0             | 0              | 0  | t  | H                  | -               | 0                             | $\dashv$      | $\dashv$ | $\dashv$      |               | ┢─            | $\vdash$   | l             |
| GOLF COURSE TURF                                      |                 | ╅  | 十       | _  | <del>                                     </del> | х  | Ħ             | X              | X  | $t^-$  | Х                  | $\neg \dagger$  | X                             |               | $\dashv$ | $\neg$        |               | <del> </del>  | <del>                                     </del> | l             |
| GRASSES GROWN FOR SEED                                |                 | +  | +       | _  | <del> </del>                                     | ┈  | X             | X              | X  | <del> </del>                                     |                    | _               | -                             | -             | $\dashv$ | $\neg$        |               | <del> </del>  | <del>                                     </del> | l             |
| NURSERY STOCK   |                 | +  | +       | _  | <del>                                     </del> | <del>                                     </del> | t             | H              | Ħ  | <del>                                     </del> | $\vdash$           | $\dashv$        | X                             | 一十            | X        |               |               | <u> </u>      | <del>                                     </del> | ĺ             |
| ORNAMENTAL AND/OR SHADE TREES                         |                 | $\top$   | +       | $\top$   | T  | <del>                                     </del> | Х             | Х              | Х  |  | Х                  | $\dashv$        | Х                             | $\neg$        | $\dashv$ | $\dashv$      |               | <u> </u>      | Х  | ĺ             |
| ORNAMENTAL GRASSES                                    |                 | +  | +       | $\top$   | m  | <del>                                     </del> | Ė             | Ë              | X  |  |                    | $\dashv$        |                               | $\neg$        | $\dashv$ | $\dashv$      |               | <u> </u>      | <del>                                     </del> | ĺ             |
| ORNAMENTAL HERBACEOUS PLANTS                          |                 | $+_{x}$  | +       | $\top$   | Х  |  | X             | X              | <del>                                     </del> | <b></b>  | Х                  | $\dashv$        | Х                             | 一十            | $\neg$   | -             |               | <u> </u>      | X  | ĺ             |
| ORNAMENTAL LAWNS AND TURF                             |                 | +-   | +       | _  | Х  | X  | X             | X              | ╅  | <del> </del>                                     | Х                  |                 | X                             | 一十            | X        | _             |               | <b></b>       | <del>                                     </del> | l             |
| ORNAMENTAL NONFLOWERING PLANTS                        |                 | ╅  | T       | $\top$   | $\vdash$   | T  | T             | $\vdash$       | T  | T  | Х                  |                 | $\neg$                        |               | $\neg$   |               |               |               | Х  | ĺ             |
| ORNAMENTAL SOD FARM (TURF)                            |                 | +-   | +       | $\top$   | Т  | х  | X             | Х              | t  | t  | Х                  | 一               | Х                             | $\neg$        | $\dashv$ | $\neg$        |               |               |  | ĺ             |
| ORNAMENTAL WOODY SHRUBS AND VINES                     |                 | _  | 十       | $\neg$   | <del>                                     </del> | <del>                                     </del> | X             | X              | †  | †  | Х                  | _               | Х                             | 一十            | 一        |               |               | <b></b>       | Х  | ĺ             |
| ORNAMENTALS (UNSPECIFIED)                             |                 | Τx   | +       | $\neg$   | <del>                                     </del> | Х  | X             | Х              | Х  | †  | Х                  | _               | Х                             | 一十            | 一        |               |               | <u> </u>      | Х  | ĺ             |
| NON-BEARING FRUIT TREES                               |                 | ┪  | ✝       | $\top$   | $\vdash$   | $\vdash$   | T             | $\vdash$       | T  | m  | 0                  | _               | $\neg$                        | $\neg$        | $\neg$   |               |               |               | Х  | ĺ             |
| RECREATION AREA LAWNS                                 |                 | $\top$   | 十       | $\top$   | H  | $\vdash$   | T             | $\vdash$       | T  | T  | Х                  |                 | Х                             | $\neg$        | $\dashv$ | $\neg$        |               |               | T  | ĺ             |
| RESIDENTIAL LAWNS                                     |                 | 1  | T       |  |  | х  | Х             |                |  |  | Χ                  |                 | Х                             |               |          |               |               |               |  |               |
| CONSUMER USE (INCL. LAWNS, ORNAMENTALS, GARDENS)      |                 |  | Τ       |  |  |  |               |                |  |  |                    |                 |                               |               |          | х             |               |               |  |               |
| CONSOLVIER USE (IIVCL. LAWINS, ORNAMIENTALS, GARDENS) |                 |  | +       |  | ├  | -  | ┞             | ┞              | -  |  |                    |                 |                               | -+            | _        |               |               |               | -  | İ             |
| NURSERY/FORESTRY                                      |                 |  |         |  |  |  |               |                |  |  |                    |                 |                               |               |          |               |               |               |  |               |
| CHRISTMAS TREE PLANTATIONS                            |                 |  | I       |  |  |  |               |                |  |  | Х                  |                 | Χ                             |               |          |               |               |               |  | ĺ             |
| CONIFERS (PLANTATIONS/NURSERIES)                      |                 |  | $\perp$ |  |  |  |               |                | L  |  | Х                  |                 | Χ                             |               |          |               |               |               |  | ĺ             |
| HYBRID COTTONWOOD/POPLAR PLANTATIONS                  |                 |  | 丄       |  | <u> </u>   | <u> </u>   | Х             | <u> </u>       | <u> </u>   |  |                    |                 |                               |               |          |               |               | L             |  | İ             |
| CONIFERS (SEED ORCHARD)                               |                 |  | $\perp$ |  | Х  |  | 0             |                |  |  | 0                  |                 |                               |               |          |               |               |               |  | İ             |
| FOREST TREES (ALL OR UNSPECIFIED)                     |                 |  | $\perp$ |  | <u></u>  | L  | 0             | Х              | <u> </u>   |  | Х                  |                 | Χ                             |               | _        |               |               |               |  | l             |
| PINE SEEDLINGS  |                 |  | _       |  | <u> </u>   | <u> </u>   | <u> </u>      | L_             | <u> </u>   |  | Χ                  | _               | _                             |               | _        |               |               |               | <u> </u>   | İ             |
| PECIALTY/INDUSTRIAL                                   |                 |  |         |  |  |  |               |                |  |  |                    |                 |                               |               |          |               |               |               |  |               |
| INDUSTRIAL ADHESIVES & COATINGS                       |                 | 1  | T       | $\top$   | Π  | Γ  | Τ             | Х              | Х  | Π  |                    | $\neg$          | $\neg$                        | $\neg \vdash$ | $\neg$   | $\neg$        |               | <u> </u>      | Π  | 1             |
| COMMERCIAL/INDUSTRIAL WATER COOLING SYSTEMS           |                 | T  | Т       | T  |  |  | Π             | Х              |  | Γ  |                    |                 |                               |               |          |               |               |               | Π  | ĺ             |
| METALWORKING CUTTING FLUIDS                           |                 |  | Ι       |  |  |  |               | Х              | Х  |  |                    |                 |                               |               |          |               |               |               |  | ĺ             |
| PAINTS (IN-CAN)                                       |                 |  | Τ       | T  |  |  |               | Х              |  |  |                    |                 |                               |               |          |               |               |               |  | ĺ             |
| PAINTS, LATEX/OIL/VARNISH (APPLIED FILM)              |                 | T  | I       | I  |  |  |               | Х              |  |  |                    |                 |                               |               |          |               |               |               |  | 1             |
| PAPER/PAPER PRODUCTS                                  |                 | I  | Ι       | $oldsymbol{\mathbb{I}}$  | L  |  |               | Х              |  |  |                    |                 |                               |               |          |               |               |               |  | 1             |
| PLASTIC PRODUCTS                                      |                 | $oldsymbol{ol}}}}}}}}}}}}$ | I       | $oldsymbol{ol}}}}}}}}}}}}}}$ |  |  | L             | Х              | Х  |  |                    |                 |                               |               |          |               |               |               |  | ĺ             |
| RUBBER PRODUCTS                                       |                 |  | Ι       |  |  |  |               | Х              |  |  |                    |                 |                               |               |          |               |               |               |  | 1             |
| SPECIALITY INDUSTRIAL PRODUCTS                        |                 | I  | I       | $oldsymbol{ol}}}}}}}}}}}}}}$ |  |  |               | Х              | Х  |  |                    |                 |                               |               |          |               |               |               |  | 1             |
| TEXTILES/TEXTILE FIBERS/CORDAGE                       |                 | $oldsymbol{\mathbb{L}}$  | I       |  |  |  |               | Х              |  |  |                    |                 |                               |               |          |               |               |               |  | 1             |
| WOOD PROTECTION TREATMENT                             |                 | T  | Т       | T  |  |  | Г             | Х              | Х  | Γ  | Х                  | 7               | $\neg$                        | T             | $\neg$   |               |               |               |  | 1             |

Source: US EPA OPPIN Query, 2017

The five crops with the highest reported usage (pounds AI and acreage treated) are bolded and cells have grey fill for ease in identifying the specific active ingredients applied to those crops.

<sup>&</sup>lt;sup>1</sup> Use sites have been generalized. Where an 'X' is indicated the active ingredient is registered for all or a majority of sites or crops that are described by the listed site. In cases where an 'O' is indicated, the active ingredient is registered for only some of the use sites or crops that are described by the listed site.

**Table 2.** Estimates of Agricultural Use of DMI (sorted by decreasing reported acreage). Reporting Time 2013-2015

| No. | Active Ingredient          | Average Annual<br>lbs AI Applied | Average Annual Base<br>Acres Treated <sup>ii</sup> |
|-----|----------------------------|----------------------------------|--|
| 1   | Propiconazole              | 1640000                          | 17180000   |
| 2   | Tebuconazole               | 1280000                          | 11530000   |
| 3   | Prothioconazole            | 510000                           | 10740000   |
| 4   | Metconazole                | 330000                           | 8680000  |
| 5   | Difenconazole              | 260000                           | 6750000  |
| 6   | Myclobutanil               | 120000                           | 2600000  |
| 7   | Triticonazole              | 10000                            | 1980000  |
| 8   | Triadimenol                | 10000                            | 1900000  |
| 9   | Imazalil <sup>iii</sup>    | <5000                            | 1420000  |
| 10  | lpconazole                 | <5000                            | 1300000  |
| 11  | Cyproconazole              | 30000                            | 820000   |
| 12  | Tetraconazole              | 40000                            | 690000   |
| 13  | Flutriafol                 | 30000                            | 400000   |
| 14  | Triflumizole <sup>iv</sup> | 100000                           | 260000   |
| 15  | Fenbuconazole              | 40000                            | 250000   |
| 16  | Fenarimol <sup>v</sup>     | <5000                            | 20000  |

Note: These are proprietary Agricultural Marketing Research Data (AMRD). Crops for which the Average Annual Pounds AI Applied or Average Annual Base Acres Treated (BAT) have been averaged and rounded to the nearest 10,000 to protect the proprietary nature of the data. <5,000 means that the average over 2013-2015 is less than 5,000 lbs.

Crops not surveyed for DMI use include: Beets, cactus, cashew, collards, cranberries, eggplant, endives, honey, hops, limes, maple syrup, melons (honeydews), mushroom, okra, onion (green), papaya, pineapple, plantain, radishes, rye, safflower, spices, sweet potatoes, tomatillo, turnips.

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ii Base Acres Treated (BAT) is the total number of unique acres in surveyed area that are treated with a specific active ingredient at least once. The area treated with a specific pesticide only contributes to the total BAT once, subsequent applications with an individual pesticide with the specified pesticide do not contribute to the BAT total.
iii Imazalil is a DMI fungicide, in the imidazole chemical group. FRAC recommends considering cross-resistance to be present against all DMI fungicides active against the same fungus.

iv Triflumizole is a DMI fungicide, in the imidazole chemical group. FRAC recommends considering crossresistance to be present against all DMI fungicides active against the same fungus.

<sup>\*</sup> Fenarimol is a DMI fungicide, in the pyrimidine chemical group. FRAC recommends considering cross-resistance to be present against all DMI fungicides active against the same fungus. US registered uses of fenarimol were cancelled in 2012, but existing stock provisions allow for the use of the chemical, as labelled, until exhaustion.

**Table 3a.** Average total DMI Fungicide usage by use site as reported by USDA NASS (2007-2016) (sorted alphabetically). vi

| AVERAGE DMI FUNGICIDE        | Pounds                                   | Percent Crop                         | •••••                      |
|------------------------------|--|--------------------------------------|----------------------------|
| COMMODITY                    | Applied (LB)<br>(rounded) <sup>vii</sup> | Treated<br>(rounded) <sup>viii</sup> | Most Recent<br>Survey Year |
| APPLES                       | 57000                                    | 20                                   | 2015                       |
| APRICOTS & NECTARINES        | 4000                                     | 25                                   | 2015                       |
| ASPARAGUS                    | 1000                                     | 10                                   | 2016                       |
| BARLEY                       | 41000                                    | 10                                   | 2011                       |
| BEANS, SNAP                  | <500                                     | ~                                    | 2016                       |
| BLACKBERRIES                 | <500                                     | ~                                    | 2015                       |
| BLUEBERRIES                  | 10000                                    | 35                                   | 2015                       |
| CABBAGE                      | <500                                     |                                      | 2016                       |
| CARROTS                      | <500                                     | 5                                    | 2016                       |
| CELERY                       | 3000                                     | 65                                   | 2016                       |
| CHERRIES, SWEET              | 31000                                    | 15                                   | 2015                       |
| CHERRIES, TART               | 5000                                     | 25                                   | 2015                       |
| CORN                         | 283000                                   | 5                                    | 2016                       |
| COTTON                       | <500                                     |                                      | 2015                       |
| CUCUMBERS                    | 1000                                     | 10                                   | 2016                       |
| GARLIC                       | 6000                                     | 55                                   | 2016                       |
| GRAPEFRUIT                   | 10000                                    | 45                                   | 2015                       |
| GRAPES                       | 97000                                    | 15                                   | 2015                       |
| GRAPES, TABLE TYPE           | 16000                                    | 30                                   | 2015                       |
| LETTUCE                      | 1000                                     | 5                                    | 2016                       |
| MELONS, CANTALOUP            | 1000                                     | 10                                   | 2016                       |
| MELONS, WATERMELON           | 15000                                    | 20                                   | 2016                       |
| OATS                         | 10000                                    | 5                                    | 2015                       |
| ONIONS, DRY & POTATOES, FALL | 1000                                     | <2.5                                 | 2016                       |
| ORANGES                      | 6000                                     | 10                                   | 2015                       |
| PEACHES                      | 13000                                    | 20                                   | 2015                       |
| PEANUTS                      | 515000                                   | 40                                   | 2013                       |
| PEARS                        | 10000                                    | 30                                   | 2015                       |
| PLUMS & PRUNES               | 3000                                     | 25                                   | 2015                       |
| RASPBERRIES                  | <500                                     | 20                                   | 2015                       |
| RICE                         | 133000                                   | 40                                   | 2013                       |
| SOYBEANS                     | 256000                                   | 5                                    | 2015                       |
| SQUASH & PUMPKINS            | 5000                                     | 10                                   | 2016                       |
| STRAWBERRIES                 | 9000                                     | 35                                   | 2016                       |
| SWEET CORN, FRESH MARKET     | 4000                                     | 10                                   | 2016                       |
| SWEET CORN, PROCESSING       | 7000                                     | 20                                   | 2016                       |
| TANGELOS                     | <500                                     | -                                    | 2015                       |
| TANGERINES                   | <500                                     | 5                                    | 2015                       |
| TOMATOES, IN THE OPEN        | 4000                                     | 10                                   | 2016                       |
| WHEAT, POST HARVEST          | 1000                                     |                                      | 2009                       |
| WHEAT, SPRING                | 684000                                   | 15                                   | 2015                       |
| WHEAT, WINTER                | 4000                                     | 5                                    | 2015                       |

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in NASS data are not reported every year. Therefore, the average pounds AI applied, Application Rate, and Percent Crop Treated (rounded) are reported for the most recent 10 years, along with the most recent reporting year.

Values have been rounded to the neared thousands. If the average reported usage of DMI fungicides on a crop was less than 500 lbs AI applied per survey year, the value is reported as "<500".

viii Percentages have been rounded up to the nearest multiple of 5, unless less than 2.5%. If the average Percent Crop Treated is less than 2.5%, it has been reported as "<2.5%".

**Table 3b.** Average DMI Fungicide usage by use site as reported by USDA NASS (2006 & 2009) (sorted alphabetically).

| COMMODITY                          | Pounds DMI Fungicides<br>Applied (LB) | Operations Reporting Usage (%) |
|------------------------------------|---------------------------------------|--------------------------------|
| BEDDING PLANTS                     | 50*                                   | 7                              |
| CUT CHRISTMAS TREES                | . (D)                                 | 10                             |
| CUT CULTIVATED GREENS              | 7250*                                 | 18                             |
| CUT FLOWERS                        | 1400*                                 | 15                             |
| DECIDUOUS TREES                    | 500*                                  | 6.5                            |
| DECIDUOUS SHRUBS                   | 1350*                                 | 12                             |
| EVERGREENS                         | 650*                                  | 11.5                           |
| FLOWERING PLANTS, POTTED, INDOOR   | 150*                                  | 4                              |
| FOLIAGE PLANTS, INDOOR             | 100*                                  | 7                              |
| FRUIT & NUT PLANTS                 | (D)                                   | 10                             |
| ORNAMENTAL GRASSES                 | (D)                                   | 8                              |
| PROPAGATIVE MATERIAL, FLORICULTURE | 200*                                  | 7                              |
| TRANSPLANTS                        | 100*                                  | 10                             |
| WOODY ORNAMENTALS & VINES, OTHER   | 400                                   | 9                              |
| NURSERY TOTALS                     | 4250*                                 | 5                              |
| FLORICULTURE TOTALS                | 9300                                  | 5                              |
| NURSERY & FLORICULTURE TOTALS**    | 9350*                                 | 4                              |

<sup>\*</sup> The average number of pounds applied does not include the pounds applied for one or more active ingredients because responses were withheld to avoid disclosing data for individual operations.

<sup>\*\*</sup>The Nursery & Floriculture Totals is a value reported by NASS. It is not the sum of the Nursery and Floriculture totals

<sup>(</sup>D) The number of pounds could not be determined because responses were withheld to avoid disclosing data for individual operations.

Table 4. DMI fungicide usage data on agricultural crops from 2013-2015 (sorted alphabetically). $^{\rm ix}$ 

| Commodity                        | Average Usage<br>(lbs Al) | Average Total Acres<br>Treated (A) | Average<br>PCT |
|----------------------------------|---------------------------|------------------------------------|----------------|
| Almonds                          | 151177                    | 1070000                            | 10             |
| Apples                           | 80000                     | 350000                             | 15             |
| Apricots                         | 1010                      | 8759                               | 15             |
| Artichoke                        | 1254                      | 12006                              | 55             |
| Asparagus                        | <5000                     | 10000                              | 15             |
| Beans (Snap, Bush, Pole, String) | <5000                     | 10000                              | 5              |
| Broccoli                         | 79                        | 757                                | <2.5           |
| Cabbage                          | <5000                     | 10000                              | 10             |
| Caneberries                      | <5000                     | 10000                              | 25             |
| Cantaloupes                      | <5000                     | 10000                              | 10             |
| Carrots                          | 929                       | 8592                               | 10             |
| Cauliflower                      | 2                         | 19                                 | <2.5           |
| Celery                           | 6490                      | 56209                              | 60             |
| Cherries                         | 50000                     | 170000                             | 15             |
| Com                              | 650000                    | 13110000                           | <2.5           |
| Cotton                           | 20000                     | 2580000                            | 5              |
| Cucumbers                        | <5000                     | 10000                              | <2.5           |
| Dry Beans/Peas                   | 30000                     | 230000                             | <2.5           |
| Garlic                           | 3280                      | 21089                              | 40             |
| Grapefruit                       | 10000                     | 50000                              | 40             |
| Grapes, Raisin                   | 20000                     | 170000                             | 15             |
| Grapes, Table                    | 20000                     | 150000                             | 30             |
| Grapes, Wine                     | 75271                     | 560000                             | 20             |
| Hazelnuts                        | 10000                     | 30000                              | 30             |
| Lemons                           | <5000                     | <5000                              | 5              |
| Lettuce                          | <5000                     | <5000                              | <1             |
| Lima Beans                       | <5000                     | <5000                              | <1             |
| Nectarine                        | 5917                      | 50305                              | ••             |
| Onions                           | <5000                     | 10000                              | 5              |
| Oranges                          | 10000                     | 70000                              | 5              |
| Peaches                          | 10000                     | 80000                              | 15             |
| Peanuts                          | 600000                    | 1400000                            | 30             |
| Pears                            | 10000                     | 30000                              | 20             |
| Pecans                           | 50000                     | 180000                             | 10             |
| Peppers                          | <5000                     | 30000                              | 20             |
| Pistachios                       | 8379                      | 69756                              | 10             |
| Plums/Prunes                     | 8508                      | 74769                              | 15             |
| Potatoes                         | 40000                     | 220000                             | 10             |
| Pumpkins                         | <5000                     | 20000                              | 5              |
| Raspberry                        | 783                       | 10000                              | *              |
| Rice                             | 200000                    | 1350000                            | 30             |

**Table 4 (continued).** DMI fungicide usage data on agricultural crops from 2013-2015 (sorted alphabetically).

| Commodity     | Average Usage<br>(lbsAI) | Average Total Acres<br>Treated (A) | Average<br>PCT |
|---------------|--------------------------|------------------------------------|----------------|
| Soybeans      | 360000                   | 8850000                            | <2.5           |
| Spinach       | <5000                    | <5000                              | <1             |
| Squash        | <5000                    | 10000                              | 5              |
| Strawberries  | 27416                    | 190000                             | 15             |
| Sugar Beets   | 90000                    | 790000                             | 10             |
| Sugarcane     | 10000                    | 70000                              | 5              |
| Sweet Com     | 20000                    | 180000                             | 15             |
| Tangelo       | 251                      | 67                                 | ~              |
| Tangerine     | 981                      | 4023                               |                |
| Tobacco       | <5000                    | <5000                              | <1             |
| Tomatoes      | 20000                    | 210000                             | 25             |
| Walnuts       | 12024                    | 76770                              | 5              |
| Watermelons   | 20000                    | 60000                              | 10             |
| Wheat, Spring | 960000                   | 1540000                            | 20             |
| Wheat, Winter | 840000                   | 16090000                           | 5              |

ix Reported data are a combination of proprietary Agricultural Marketing Research Data (AMRD) and California Pesticide Use Reporting data. Crops for which the average annual total pounds applied or average annual acreage has been acquired from AMRD have been averaged and rounded to the nearest 10,000 to protect the proprietary nature of the data. *Italicized* crops are primarily grown in California (≥80% of acreage). Therefore, the average pounds of DMI fungicides applied and the average acreage over which they were applied to California crops during 2013 to 2015 are from CalPUR and are reported as unrounded averages.

Average Total Acres Treated is the average number of acres treated with all DMI fungicide applications in a year, including more than a single DMI AI and DMI reapplications.

Average percent of crop treated - Values are calculated by averaging by year, averaging across all years, & rounding to the nearest multiple of 5. If the estimated value is less than 2.5, then the value is labeled <2.5. If the estimated value is less than 1, then the value is labeled <1. All PCT values were derived from AMRD.

#### Message

From: Jennings, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B3E06D481ADC45F296232CF2DE82A8B7-JENNINGS, SUSAN]

**Sent**: 9/4/2018 5:28:35 PM

To: sgumbis@cdc.gov; thenning@cdc.gov

CC: Jean Patel [vzp4@cdc.gov]
Subject: FW: Environment report

Attachments: Triazole and DeMethylation and Other Fungicides.pdf

I sent the email below to Jean, but got an out of office response.

Wanted to be sure this goes where it needs to.

From: Jennings, Susan

Sent: Tuesday, September 04, 2018 1:21 PM

To: 'Patel, Jean (CDC/OID/NCEZID)' <vzp4@cdc.gov>

Subject: RE: Environment report

Thank you, Jean.

I have attached the memo that you asked about.

I am going through the comments now and will be sending you another version addressing comments that may have not been completely addressed (just a few).

Thanks again,

Susan.

From: Patel, Jean (CDC/OID/NCEZID) [mailto:vzp4@cdc.gov]

Sent: Friday, August 31, 2018 4:01 PM

To: Jennings, Susan < Jennings. Susan@epa.gov>

Subject: Environment report

Susan

Attached are two documents.

- The report with EPA comments. For each EPA comment I provide a response. The edits appear in document 2. Some comments were hard to respond to. For example, there is mention of a memo with numbers and a recommendation to use those numbers. I need the memo. This was sent to CDC but I don't have it and need to make changes soon.
- 2. The most current version of the report with edits based upon EPA comments.

Thanks,

Jean

Jean B. Patel PhD, D(ABMM)
Science Team Lead
Antibiotic Resistance Coordination & Strategy

NCEZID/DHQP/OD 404.639.0361 | jpatel1@cdc.gov From: Jennings, Susan [Jennings.Susan@epa.gov]

**Sent**: 8/1/2017 12:54:28 PM

To: Heather.Harbottle@fda.hhs.gov; Jeff.Gilbert@fda.hhs.gov; Julius Fajardo [Julius.Fajardo@ARS.USDA.GOV]; Rose

Hammond [Rose.Hammond@ARS.USDA.GOV]

CC: Johnson, Hope [Johnson.Hope@epa.gov]; Garvie, Heather [Garvie.Heather@epa.gov]; Jean Patel [vzp4@cdc.gov];

Michael Craig [bez7@cdc.gov]

**Subject**: FW: comments from CDC

Hello all,

Thanks for your comments. Below is what we've received from CDC.

Thanks to all,

Susan.

From: Patel, Jean (CDC/OID/NCEZID) [mailto:vzp4@cdc.gov]

**Sent:** Friday, July 28, 2017 11:35 AM

To: Johnson, Hope < Johnson. Hope@epa.gov>

Cc: Jennings, Susan < Jennings.Susan@epa.gov>; Craig, Michael R. (CDC/OID/NCEZID) < bez7@cdc.gov>

Subject: comments from CDC

Sorry for being a bit late.

Streptomycin & Tetracycline

# **Deliberative Process / Ex. 5**

From: Johnson, Hope [mailto:Johnson.Hope@epa.gov]

Sent: Thursday, July 20, 2017 10:54 AM

To: Sow, Fatima <<u>Sow.Fatima@epa.gov</u>>; Jennings, Susan <<u>Jennings.Susan@epa.gov</u>>; Kough, John <<u>Kough.John@epa.gov</u>>; Collins, Samantha <<u>collins.samantha@epa.gov</u>>; Chandgoyal, Tara <<u>Chandgoyal.Tara@epa.gov</u>>; Garvie, Heather <<u>Garvie.Heather@epa.gov</u>>; Giles-Parker, Cynthia <<u>Giles-Parker.Cynthia@epa.gov</u>>; Carl Schultze <<u>Carl.P.Schulze@aphis.usda.gov</u>>; Julius Fajardo <<u>Julius.Fajardo@ARS.USDA.GOV</u>>; Harbottle, Heather (FDA/CVM) <<u>Heather.Harbottle@fda.hhs.gov</u>>; Patel, Jean (CDC/OID/NCEZID) <<u>vzp4@cdc.gov</u>>; Gilbert, Jeffrey M (FDA/CVM) <<u>Jeff.Gilbert@fda.hhs.gov</u>>; Craig, Michael R. (CDC/OID/NCEZID) <<u>bez7@cdc.gov</u>>; Rose Hammond <<u>Rose.Hammond@ARS.USDA.GOV</u>>
Cc: Cook, Colwell <<u>cook.colwell@epa.gov</u>>; Britton, Cathryn <<u>Britton.Cathryn@epa.gov</u>>; Kaul, Monisha <<u>Kaul.Monisha@epa.gov</u>>

Subject: RE: Federal interagency Antibiotic Resistance Call

Thank you all again for your participation today on the call. Attached are all the Resistance Review documents for your review in one place. Our BEAD division is determining whether or not we can provide the draft Benefits documents as an FYI. The Benefits documents include discussion on efficacy and alternatives. We will forward those documents to you if we can as soon as possible.

We would appreciate any comments you have- please send as soon as possible and hopefully no later than COB Wednesday 7/26/2017.

Please send any comments to Susan Jennings and cc: myself (Hope Johnson) and Fatima Sow.

Again, please note that we are in the Risk Management stage of the review. In the coming few weeks, we will begin briefings for our Management along with drafting the Proposed Decision documents for each AI (active ingredient) in preparation for the Public Process. We hope to begin the Public Process by the beginning of October of this year. It will include a 30 day comment period and allows the public to look at all supporting documents associated with the Proposed Decision (Health Effects Division risk assessment, Environmental Fate and Effects Division risk assessment, Biological and Economic Analysis Division Benefits assessment, Resistance Review (former 152), proposed labels). The Proposed Decision will discuss any mitigation we are proposing for that specific AI's new use.

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Please feel free to contact me if you have questions on the process.

Thank you,

Hope A. Johnson

Product Manager 21 U.S. Environmental Protection Agency Office of Pesticide Programs Registration Division Fungicide Branch Phone: 703-305-5410 Mail Code 7505P

From: Johnson, Hope

Sent: Thursday, July 20, 2017 8:18 AM

**To:** Sow, Fatima < Sow.Fatima@epa.gov >; Jennings, Susan < Jennings.Susan@epa.gov >; Kough, John

< Kough. John@epa.gov>; Collins, Samantha < collins. samantha@epa.gov>; Chandgoyal, Tara

< Chandgoyal. Tara@epa.gov >; Garvie, Heather < Garvie. Heather@epa.gov >; Giles-Parker, Cynthia < Giles-

Parker.Cynthia@epa.gov>; Carl Schultze <Carl.P.Schulze@aphis.usda.gov>; Julius Fajardo

<Julius.Fajardo@ARS.USDA.GOV>;Heather.Harbottle@fda.hhs.gov; Jean Patel

<vzp4@cdc.gov>;Jeff.Gilbert@fda.hhs.gov; Michael Craig <bez7@cdc.gov>; Rose Hammond

<Rose.Hammond@ARS.USDA.GOV>

Cc: Cook, Colwell < cook.colwell@epa.gov >; Britton, Cathryn < Britton.Cathryn@epa.gov >

Subject: RE: Federal interagency Antibiotic Resistance Call

The original streptomycin grapefruit/tomato 152 review is attached here. Previously only the addendum was attached. This is the complete document .

Hope A. Johnson

Product Manager 21 U.S. Environmental Protection Agency Office of Pesticide Programs Registration Division Fungicide Branch Phone: 703-305-5410 Mail Code 7505P From: Sow, Fatima

Sent: Wednesday, July 19, 2017 4:49 PM

To: Jennings, Susan < Jennings.Susan@epa.gov >; Kough, John < Kough.John@epa.gov >; Collins, Samantha

<collins.samantha@epa.gov>; Chandgoyal, Tara < Chandgoyal.Tara@epa.gov>; Garvie, Heather

<<u>Garvie.Heather@epa.gov</u>>; Johnson, Hope <<u>Johnson.Hope@epa.gov</u>>; Giles-Parker, Cynthia <<u>Giles-</u>

Parker.Cynthia@epa.gov>; Carl Schultze <Carl.P.Schulze@aphis.usda.gov>; Julius Fajardo

<Julius.Fajardo@ARS.USDA.GOV>;Heather.Harbottle@fda.hhs.gov; Jean Patel

<<u>vzp4@cdc.gov</u>>;<u>Jeff.Gilbert@fda.hhs.gov</u>; Michael Craig <<u>bez7@cdc.gov</u>>; Rose Hammond

<<u>Rose.Hammond@ARS.USDA.GOV</u>>

Subject: RE: Federal interagency Antibiotic Resistance Call

Documents to be discussed are attached.

-----Original Appointment-----

From: Jennings, Susan

Sent: Monday, June 19, 2017 10:19 AM

To: Jennings, Susan; Kough, John; Collins, Samantha; Chandgoyal, Tara; Garvie, Heather; Johnson, Hope; Giles-

Parker, Cynthia; Carl Schultze; Julius Fajardo; Heather. Harbottle@fda.hhs.gov; Jean

Patel; Jeff. Gilbert@fda.hhs.gov; Michael Craig; Rose Hammond

Cc: Sow, Fatima

Subject: Federal interagency Antibiotic Resistance Call

When: Thursday, July 20, 2017 8:00 AM-10:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: Conference call # 866-299-3188, code 7063558524

Documents to be discussed are attached to this invitation.

This is just a hold until we find a time that works for Federal Partners. Final meeting will be scheduled for 2 hours (but may be shorter).

#### Message

From: Johnson, Hope [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3B0950574252454393A8915C2F21A711-HOPE JOHNSON]

**Sent**: 7/27/2017 12:11:34 PM

To: Patel, Jean (CDC/OID/NCEZID) [vzp4@cdc.gov]

CC: Jennings, Susan [Jennings.Susan@epa.gov]; Giles-Parker, Cynthia [Giles-Parker.Cynthia@epa.gov]; Sow, Fatima

[Sow.Fatima@epa.gov]; Garvie, Heather [Garvie.Heather@epa.gov]

Subject: RE: Federal interagency Antibiotic Resistance Call

We will welcome your comments whenever. Thanks for taking the time. We have briefings starting the week of 8/7 which is why we are a little time crunched but we can add in your comments last minute if need be.

Thanks, Hope

Hope A. Johnson
Product Manager 21
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division
Fungicide Branch
Phone: 703-305-5410
Mail Code 7505P

From: Patel, Jean (CDC/OID/NCEZID) [mailto:vzp4@cdc.gov]

Sent: Thursday, July 27, 2017 8:08 AM

To: Johnson, Hope <Johnson.Hope@epa.gov>
Cc: Jennings, Susan <Jennings.Susan@epa.gov>

Subject: RE: Federal interagency Antibiotic Resistance Call

Could I please have a few more days for comments? I am on vacation and also trying to get input from others at CDC. Thanks for considering.

From: Johnson, Hope < Johnson. Hope@epa.gov>

Date: July 20, 2017 at 9:55:00 AM CDT

**To:** Rose Hammond <a href="Rose.Hammond@ARS.USDA.GOV">Rose Hammond@ARS.USDA.GOV">Rose Hammond@ARS.USDA.GOV</a>, Chandgoyal, Tara <a href="Chandgoyal.Tara@epa.gov">Chandgoyal.Tara@epa.gov</a>, Patel, Jean (CDC/OID/NCEZID) <a href="CDA/CVM">CDC/OID/NCEZID</a>) <a href="CDA/CVM">CDC/OID/NCEZID</a>) <a href="CDA/CVM">COMPARTION OF TARABON OF

**Cc:** Britton, Cathryn < <u>Britton.Cathryn@epa.gov</u>>, Cook, Colwell < <u>cook.colwell@epa.gov</u>>, Kaul, Monisha < Kaul.Monisha@epa.gov>

**Subject:** RE: Federal interagency Antibiotic Resistance Call

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an FYI. The Benefits documents include discussion on efficacy and alternatives. We will forward those documents to you if we can as soon as possible.

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Please send any comments to Susan Jennings and cc: myself (Hope Johnson) and Fatima Sow.

Again, please note that we are in the Risk Management stage of the review. In the coming few weeks, we will begin briefings for our Management along with drafting the Proposed Decision documents for each AI (active ingredient) in preparation for the Public Process. We hope to begin the Public Process by the beginning of October of this year. It will include a 30 day comment period and allows the public to look at all supporting documents associated with the Proposed Decision (Health Effects Division risk assessment, Environmental Fate and Effects Division risk assessment, Biological and Economic Analysis Division Benefits assessment, Resistance Review (former 152), proposed labels). The Proposed Decision will discuss any mitigation we are proposing for that specific AI's new use.

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Please feel free to contact me if you have questions on the process.

Thank you,

Hope A. Johnson
Product Manager 21
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division
Fungicide Branch
Phone: 703-305-5410

From: Johnson, Hope

Mail Code 7505P

Sent: Thursday, July 20, 2017 8:18 AM

To: Sow, Fatima <Sow.Fatima@epa.gov>; Jennings, Susan <Jennings.Susan@epa.gov>; Kough, John

<Kough John@epa.gov>; Collins, Samantha <collins.samantha@epa.gov>; Chandgoyal, Tara

< Chandgoyal. Tara@epa.gov>; Garvie, Heather < Garvie. Heather@epa.gov>; Giles-Parker, Cynthia < Giles-

Parker.Cynthia@epa.gov>; Carl Schultze <Carl.P.Schulze@aphis.usda.gov>; Julius Fajardo

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Jeff.Gilbert@fda.hhs.gov; Michael Craig <bez7@cdc.gov>; Rose Hammond <Rose.Hammond@ARS.USDA.GOV>

Cc: Cook, Colwell <cook.colwell@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>

Subject: RE: Federal interagency Antibiotic Resistance Call

The original streptomycin grapefruit/tomato 152 review is attached here. Previously only the addendum was attached. This is the complete document.

Hope A. Johnson
Product Manager 21
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division

Fungicide Branch Phone: 703-305-5410 Mail Code 7505P

From: Sow, Fatima

**Sent:** Wednesday, July 19, 2017 4:49 PM

To: Jennings, Susan < Jennings. Susan@epa.gov>; Kough, John < Kough. John@epa.gov>; Collins, Samantha

<collins.samantha@epa.gov>; Chandgoyal, Tara < Chandgoyal.Tara@epa.gov>; Garvie, Heather

<Garvie.Heather@epa.gov>; Johnson, Hope <Johnson.Hope@epa.gov>; Giles-Parker, Cynthia <Giles-

Parker.Cynthia@epa.gov>; Carl Schultze < Carl.P.Schulze@aphis.usda.gov>; Julius Fajardo

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<u>Jeff.Gilbert@fda.hhs.gov</u>; Michael Craig <br/>
<u>Jez7@cdc.gov</u>>; Rose Hammond <<u>Rose.Hammond@ARS.USDA.GOV</u>>

Subject: RE: Federal interagency Antibiotic Resistance Call

Documents to be discussed are attached.

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From: Jennings, Susan

Sent: Monday, June 19, 2017 10:19 AM

**To:** Jennings, Susan; Kough, John; Collins, Samantha; Chandgoyal, Tara; Garvie, Heather; Johnson, Hope; Giles-Parker, Cynthia; Carl Schultze; Julius Fajardo; Heather. Harbottle@fda.hhs.gov; Jean Patel; Jeff. Gilbert@fda.hhs.gov; Michael

Craig; Rose Hammond Cc: Sow, Fatima

**Subject:** Federal interagency Antibiotic Resistance Call

When: Thursday, July 20, 2017 8:00 AM-10:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: Conference call # 866-299-3188, code 7063558524

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#### Message

From: Johnson, Hope [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3B0950574252454393A8915C2F21A711-HOPE JOHNSON]

**Sent**: 7/20/2017 3:26:46 PM

To: Giles-Parker, Cynthia [Giles-Parker.Cynthia@epa.gov]; Sow, Fatima [Sow.Fatima@epa.gov]; Garvie, Heather

[Garvie.Heather@epa.gov]

**Subject**: FW: Federal interagency Antibiotic Resistance Call

Attachments: Oxytetracycline 152 Fireline 17WP 07032017.doc; Kasugamin Arysta 152 -07-03-2017.docx; Streptomycin 152

Firewall 50WP 07032017 .doc; Sec 3 grpfrt tomato strep 152.pdf

RD needs to review these and send John and the team any comments as well that we have on top of what we discussed with them Tuesday morning. Please send me any of your comments on these.

Hope A. Johnson
Product Manager 21
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division
Fungicide Branch
Phone: 703-305-5410
Mail Code 7505P

From: Johnson, Hope

Sent: Thursday, July 20, 2017 10:53 AM

To: Sow, Fatima <Sow.Fatima@epa.gov>; Jennings, Susan <Jennings.Susan@epa.gov>; Kough, John

<Kough.John@epa.gov>; Collins, Samantha <collins.samantha@epa.gov>; Chandgoyal, Tara

<Chandgoyal.Tara@epa.gov>; Garvie, Heather <Garvie.Heather@epa.gov>; Giles-Parker, Cynthia <Giles-</p>

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<vzp4@cdc.gov>; 'Jeff.Gilbert@fda.hhs.gov' <Jeff.Gilbert@fda.hhs.gov>; 'Michael Craig' <bez7@cdc.gov>; 'Rose
Hammond' <Rose.Hammond@ARS.USDA.GOV>

**Cc:** 'Cook, Colwell' <cook.colwell@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>; Kaul, Monisha <Kaul.Monisha@epa.gov>

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< Chandgoyal. Tara@epa.gov>; Garvie, Heather < Garvie. Heather@epa.gov>; Giles-Parker, Cynthia < Giles-

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Craig; Rose Hammond

Cc: Sow, Fatima

**Subject:** Federal interagency Antibiotic Resistance Call

When: Thursday, July 20, 2017 8:00 AM-10:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: Conference call # 866-299-3188, code 7063558524

Documents to be discussed are attached to this invitation.

This is just a hold until we find a time that works for Federal Partners. Final meeting will be scheduled for 2 hours (but may be shorter).

#### Appointment

Patel, Jean (CDC/OID/NCEZID) [vzp4@cdc.gov] From:

Sent: 9/5/2018 7:35:29 PM

To: Patel, Jean (CDC/OID/NCEZID) [vzp4@cdc.gov]; Sims, Diann [Sims.Diann@epa.gov]; Suarez, Mark

[Suarez.Mark@epa.gov]; Craig, Michael R. (CDC/OID/NCEZID) [bez7@cdc.gov]; Pantino, Elizabeth (CDC/OID/NCEZID)

[ymt0@cdc.gov]; Jennings, Susan [Jennings.Susan@epa.gov]

CC: Miller, Wynne [Miller.Wynne@epa.gov]

Subject: Fwd: Resolving the EPA comments

Attachments: AMR Env Forum Report combined 083118 EPA Pesticide Comments.docx; ATT00001.htm

Location: Teleconference

9/6/2018 5:00:00 PM Start: 9/6/2018 6:00:00 PM End:

Show Time As: Tentative

FYI, I'm talking to CDC tomorrow about | Deliberative Process / Ex. 5

Sent from my iPhone

Begin forwarded message:

From: "Patel, Jean (CDC/OID/NCEZID)" <vzp4@cdc.gov>

**To:** "Suarez, Mark" < Suarez. Mark@epa.gov> Subject: FW: Resolving the EPA comments

----Original Appointment----

From: Patel, Jean (CDC/OID/NCEZID) [mailto:vzp4@cdc.gov]

Sent: Wednesday, September 05, 2018 8:57 AM

To: Patel, Jean (CDC/OID/NCEZID); Craig, Michael R. (CDC/OID/NCEZID); Pantino,

Elizabeth (CDC/OID/NCEZID); Jennings, Susan

Subject: Resolving the EPA comments

When: Thursday, September 06, 2018 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US &

Canada).

Where: Teleconference

Susan – please forward.

Conference Line/Code / Ex. 6

Leader Passcode: Participant Passco

#### Appointment

From: Suarez, Mark [Suarez.Mark@epa.gov]

**Sent**: 9/5/2018 7:35:26 PM

To: Sims, Diann [Sims.Diann@epa.gov]
CC: Miller, Wynne [Miller.Wynne@epa.gov]

**Subject**: Fwd: Resolving the EPA comments

Attachments: AMR Env Forum Report combined\_083118 EPA Pesticide Comments.docx; ATT00001.htm

Location: Teleconference

**Start**: 9/6/2018 5:00:00 PM **End**: 9/6/2018 6:00:00 PM

Show Time As: Tentative

FYI, I'm talking to CDC tomorrow

**Deliberative Process / Ex. 5** 

Sent from my iPhone

Begin forwarded message:

From: "Patel, Jean (CDC/OID/NCEZID)" < vzp4@cdc.gov>

**To:** "Suarez, Mark" < Suarez.Mark@epa.gov > Subject: FW: Resolving the EPA comments

----Original Appointment----

From: Patel, Jean (CDC/OID/NCEZID) [mailto:vzp4@cdc.gov]

Sent: Wednesday, September 05, 2018 8:57 AM

To: Patel, Jean (CDC/OID/NCEZID); Craig, Michael R. (CDC/OID/NCEZID); Pantino,

Elizabeth (CDC/OID/NCEZID); Jennings, Susan

Subject: Resolving the EPA comments

When: Thursday, September 06, 2018 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US &

Canada).

Where: Teleconference

Susan – please forward.

USA | Conference Line/Code / Ex. 6

Leader Passcode:

Participant Passcod

Conference Line/Code / Ex. 6

#### Message

From: Maignan, Tawanda [Maignan.Tawanda@epa.gov]

**Sent**: 3/8/2016 4:42:48 PM

To: Craig, Michael R. (CDC/OID/NCEZID) [bez7@cdc.gov]

CC: Jennings, Susan [Jennings.Susan@epa.gov]; Madden, Barbara [Madden.Barbara@epa.gov]; Rosenblatt, Daniel

[Rosenblatt.Dan@epa.gov]; Herndon, George [Herndon.George@epa.gov]; Patel, Jean (CDC/OID/NCEZID)

[vzp4@cdc.gov]; Wan, Ellen (CDC/OID/NCEZID) [gqj0@cdc.gov]

**Subject**: RE: Florida Citrus Greening S18 for Antibiotics

Hello Dr. Craig,

We appreciate your timely response and will take your recommendations under consideration when finalizing the section 18 specific exemptions. Again, thank you for your time last week and offering this feedback.

Regards,

Tawanda

Tawanda Maignan
Emergency Response Team Leader
Registration Division | Office of Pesticide Programs
Office of Chemical Safety & Pollution Prevention
U.S. Environmental Protection Agency (7505P)
1200 Pennsylvania Avenue, NW | Washington, DC 20460

Tel: (703) 308-8050 | Maignan. Tawanda@epa.gov

From: Craig, Michael R. (CDC/OID/NCEZID) [mailto:bez7@cdc.gov]

Sent: Monday, March 07, 2016 11:27 PM

To: Maignan, Tawanda < Maignan. Tawanda@epa.gov>

Cc: Jennings, Susan < Jennings.Susan@epa.gov>; Madden, Barbara < Madden.Barbara@epa.gov>; Rosenblatt, Daniel

<Rosenblatt.Dan@epa.gov>; Herndon, George <Herndon.George@epa.gov>; Patel, Jean (CDC/OID/NCEZID)

<vzp4@cdc.gov>; Wan, Ellen (CDC/OID/NCEZID) <gqj0@cdc.gov>

Subject: RE: Florida Citrus Greening S18 for Antibiotics

### Tawanda:

We appreciate the opportunity to discuss CDC's concerns about the use of streptomycin and oxytetracycline as a pesticide for greening disease in Florida citrus.

Per your request, here is a list of proposed mitigation steps from CDC:

# **Deliberative Process / Ex. 5**

## **Deliberative Process / Ex. 5**

Thank you, Michael

From: Maignan, Tawanda [mailto:Maignan.Tawanda@epa.gov]

Sent: Thursday, March 03, 2016 6:11 PM

To: Craig, Michael R. (CDC/OID/NCEZID) < bez7@cdc.gov>

Cc: Jennings, Susan < Jennings.Susan@epa.gov >; Madden, Barbara < Madden.Barbara@epa.gov >; Rosenblatt, Daniel

<<u>Rosenblatt.Dan@epa.gov</u>>; Herndon, George <<u>Herndon.George@epa.gov</u>>

Subject: Florida Citrus Greening S18 for Antibiotics

Importance: High

Mr. Craig,

Again, thank you for taking the time to speak with use today and offer additional clarification on CDC's position with respect to the Section 18 for antibiotics and other uses. As discussed, we would like CDC's assistance/guidance with the type of monitoring we would like for Florida to conduct. For consideration, the following is a general summary that was provided by EPA's 152 Team on monitoring:

## **Deliberative Process / Ex. 5**

# **Deliberative Process / Ex. 5**

We look forward to your feedback and the contact information for Ms. Beth Bell at your earliest convenience.

Regards, Tawanda

Tawanda Maignan
Emergency Response Team Leader
Registration Division | Office of Pesticide Programs
Office of Chemical Safety & Pollution Prevention
U.S. Environmental Protection Agency (7505P)
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Tel: (703) 308-8050 | Maignan.Tawanda@epa.gov